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PART II

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

FOOD LABELING

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER A—GENERAL

PART 1—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND THE FAIR PACKAGING AND LABELING ACT

U.S. Recommended Daily Allowances for Infants

In the FEDERAL REGISTER of August 2, 1973 (38 FR 20745), the Commissioner of Food and Drugs published a proposal to amend 21 CFR 1.17 by revising paragraph (h)(1) to permit use of the U.S. Recommended Daily Allowances (U.S. RDA's) for vitamins and minerals established for infants in § 125.1(b) (38 FR 20717) in nutrition labeling of infant, baby, and junior-type foods.

Eight comments were received: three from consumers, two from professional organizations, one from a trade association, and two from manufacturers. The comments received and the Commissioner's responses are as follows:

1. Comments were received from three consumers supporting the nutrition labeling of infant, baby, and junior-type foods. Each comment indicated that the presence of the nutrition label information would assist in selecting a more nutritious diet for infants and small children.

2. The American Dietetic Association commented that it would like included in the regulation a statement that the U.S. RDA levels for infants will be updated as required by changes in the "Recommended Daily Allowances" of the Food and Nutrition Board of the National Academy of Sciences/National Research Council (NAS/NRC).

The Commissioner advises that a provision currently appears in § 125.1(b)(1) (38 FR 20717) stating that the U.S. RDA's are subject to reconsideration for possible amendment when the Food and Nutrition Board, NAS/NRC, revises the "Recommended Dietary Allowances." This applies to all of the U.S. RDA values established in § 125.1.

3. Several comments took issue with the proposed U.S. RDA for protein for infants.

The Committee on Nutrition, American Academy of Pediatrics, commented that an infant U.S. RDA of 20 grams for a protein with a protein efficiency ratio (PER) equal to or greater than casein was too high. The Committee recommended that 16 grams of protein be the U.S. RDA. The Committee pointed out that a protein level of 16 grams was consistent with the protein level set in the "Recommended Dietary Allowances" of the Food and Nutrition Board, NAS/NRC, in its 1968 report. The Committee comment stated that its members feel that any inflation of protein standards may actually result in greater incidence of protein deficiency in other countries where protein shortages often occur. The impact of the United States regulations in other countries could be serious according to the Committee on Nutrition.

The National Canners Association and the Gerber Products Company commented that, for infants less than 12 months of age, the U.S. RDA for protein should be 16 grams when the PER is equal to or greater than casein, and 23 grams if the PER is less than casein.

The Mead Johnson Company proposed that the Commissioner set the U.S. RDA at the daily protein level for infants of 1 year of age set by the Food and Nutrition Board, NAS/NRC.

In general, these comments asserted that the proposed U.S. RDA's for infants of 20 grams and 28 grams were set for children under 4 years of age and are not consistent with the values in the regulation on infant formulae (21 CFR 125.5) which establishes a protein content of 1.8 grams per 100 kilocalories. The caloric intake of a 1-year-old infant weighing 9 kilograms is approximately 900 kilocalories, and the protein requirement would be approximately 16 grams per day.

The Commissioner notes that the Food and Nutrition Board of the NAS/NRC established a similar requirement for protein per kilogram per day, and related that to a 9-kilogram infant in its 1968 Recommended Dietary Allowances. The body weight used by the Food and Nutrition Board in their Recommended Dietary Allowances, and that suggested by the Committee on Nutrition, American Academy of Pediatrics, 9 kilograms, represents approximately the median or 50th percentile weight for the 9-month-old male infant according to standard weight tables for infants, Nelson, W.E., V.C. Vaughan, and R.J. McKay, "Textbook of Pediatrics," 9th edition, W.B. Saunders Co. (1969). The 50th percentile weight for the 1-year-old male infant is 10.07 kilograms.

The Food and Drug Administration, in developing the currently established U.S. RDA's (21 CFR 125.1), set values at the upper level for a given population group in order to provide a labeling basis adequate for all of the persons in the group. Following this policy, the U.S. RDA for protein for infants should relate to the higher weight and should be 18 grams for protein equal to or better than casein. This value is the product of the 1.8 grams of protein per kilogram per day multiplied by a body weight of 10 kilograms which is the 50th percentile of the 1 year old. On this basis, the U.S. RDA for protein with a protein quality less than casein would be 25 grams, using a factor of 70 percent as the average PER value for dietary protein of a quality lower than casein. The regulation as set forth below adopts these two values as the U.S. RDA's for protein for infants.

4. The National Canners Association commented that there is a need for different U.S. RDA's for infants and for children under 4 years of age and that this is consistent with finding 13 in the Findings of Fact for Part 125 published on August 2, 1973 (38 FR 20713).

The Gerber Products Company also commented on the need for different U.S. RDA's for labeling food for infants and for children under 4 years of age. They proposed that 21 CFR 1.17(h)(1) be revised to read as follows:

Except where expressly covered by § 125.5 of this chapter, infant, baby, and junior-type food marketed and promoted primarily for infants and children under 4 years of age shall include nutrition information on the label and in labeling in compliance with this section except that the U.S. RDA levels for either infants from birth to 12 months of age or children under 4 years of age or both as contained in § 125.1(b) of this chapter shall be used. For the purposes of labeling these foods with a percent of the U.S. RDA for protein, a value of 20 grams of protein shall be the U.S. RDA value for protein with a protein efficiency ratio (PER) equal to or greater than casein, and 28 grams if the PER of the protein is less than the PER of casein but greater than 20 percent of casein.

The Commissioner has carefully considered the use of either or both the U.S. RDA values for vitamins, minerals, and protein for infants and children under 4 years of age on the labels of food offered for infants and for children under 4 years of age. Based on the comments received and other available information, the Commissioner concludes that there is a need for different U.S. RDA values for infants and for children under 4 years of age, as requested by the Gerber Company and the National Canners Association.

The petitioners pointed out that a few baby foods are promoted for both infants and children under 4 years of age. The Commissioner concludes that, because of the uniqueness of these two limited categories of foods, dual declaration of nutrients pursuant to § 1.17 should be permitted in this instance. Some "infant foods" can be used well beyond 1 year, and some "junior-type foods" can be used earlier than 1 year. The Commissioner therefore concludes that those infant or junior-type foods which are represented for both uses may include nutritional labeling based on the U.S. RDA both for infants and for children under 4 years of age. It appears that very few foods are represented or intended for both of these age groups, but such products properly should bear nutrition labeling for both groups.

The Commissioner recognizes that permitting such dual declaration, even in these limited circumstances, could result in misleading promotion if the U.S. RDA values for infants were emphasized in labeling and advertising, because it would artificially inflate the nutritional value of the food for use in children under 4 years of age. Accordingly, the final order provides that, where such dual declaration is used, it must also be included in all labeling in a way that gives equal prominence to both values and does not emphasize one of them.

The Commissioner emphasizes that dual declaration is permitted under these very limited circumstances because of the unique nature of these products. The provisions of § 1.17 already state that dual declaration for adults and children under 4 years of age is not permitted. The Commissioner has again reviewed that matter and concludes that other

forms of dual declaration remain unjustified.

5. The Mead Johnson Company commented that a protein with a PER of 20 percent that of casein has very little nutritional value for the infant and, if used to supply most of the protein needs for the infant, would not support normal growth. A value of 40 percent of casein would allow most of the average proteins in the diet to be included in contributing to the total protein intake.

The Commissioner agrees and has modified the proposal to require protein quality of 40 percent that of casein in order to make a U.S. RDA declaration for infant food. The increase in the minimum protein quality for which a U.S. RDA claim can be made from 20 percent of casein quality to 40 percent of casein quality would in the opinion of the Commissioner make very little, if any, practical change in the actual labeling of the protein in foods for infants. The Commissioner concludes that a protein with a PER of 20 percent that of casein is insufficient to promote adequate growth in infants whereas protein with a PER of 40 percent that of casein can be utilized for this purpose. The need to provide protection for infants, one of the most vulnerable population groups in relation to inadequate nutrition, is satisfied in part with this increase in the minimum protein quality. The 40-percent value will only apply to the U.S. RDA for protein for infants (under 12 months of age).

On the basis of a review of the comments, the Commissioner has modified the nutrition labeling proposal related to labeling infant, baby, and junior-type food marketed and promoted solely for infants, or for infants and children under 4 years of age, to establish a U.S. RDA for protein for infants, increase the minimum protein quality required to make a U.S. RDA label declaration, and define when the U.S. RDA's for children under 4 years of age can be used in labeling.

Background material in support of this regulation is on public display in the office of the Hearing Clerk, Food and Drug Administration, Rm. 6-86, 5600 Fishers Lane, Rockville, MD 20852.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201, 403, 701(a), 52 Stat. 1040–1042 as amended, 1047–1048 as amended, 1055; 21 U.S.C. 321, 343, 371 (a)) and under authority delegated to the Commissioner (21 CFR 2.120), Part 1 is amended by revising § 1.17(h)(1) to read as follows:

§ 1.17 Food; nutrition labeling.

* * * * *

(h) * * *

(1) (i) Except where expressly covered by § 125.5 of this chapter, infant, baby, and junior-type food promoted for infants and children under 4 years of age shall include nutrition information on the label and in labeling in compliance with this section, except that the U.S. Recommended Daily Allowance (U.S. RDA) levels for infants from birth to 12 months of age or for children under 4 years of age contained in § 125.1(b) of this chapter shall be used in lieu of the U.S. RDA levels contained in paragraph (c)(7)(iv) of this section.

(ii) Both the U.S. RDA levels for infants from birth to 12 months of age and the U.S. RDA values for children under 4 years of age may be declared for foods represented or intended for use by both infants and children under 4 years of age. If such dual declaration is used on any label, it shall also be included in all labeling, and equal prominence shall be given to both values in all promotional material.

(iii) For the purposes of labeling these foods with a percent of the U.S. RDA for protein for infants, a value of 18 grams of protein shall be the U.S. RDA value for protein with a protein efficiency ratio (PER) equal to or greater than casein, and 25 grams if the PER of the protein is less than the PER of casein but greater than 40 percent of casein. For purposes of labeling foods for children under 4 years of age with a percent of the U.S. RDA for protein, a value of 20 grams of protein shall be the U.S. RDA value for protein with a PER equal to or greater than casein, and 28 grams if the PER of the protein is less than the PER of casein but greater than 20 percent of casein.

(iv) Total protein with a PER less than 40 percent of the PER of casein may not be stated on the label in terms of percentage U.S. RDA for infants, and the statement of protein content in grams per serving under paragraph (c)(4) of this section shall be modified by the statement "not a significant source of protein for infants" immediately adjacent to the protein content statement regardless of the actual amount of protein present.

* * * * *

Effective date. This regulation shall be effective on January 1, 1975.

(Secs. 201, 403, 701(a), 52 Stat. 1040–1042 as amended, 1047–48 as amended, 1055; (21 U.S.C. 321, 343, 371(a)))

Dated: June 7, 1974.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.74-13484 Filed 6-13-74;8:45 am]

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

PART 30—TABLE SIRUPS

Establishment of Standards of Identity

In a notice of proposed rule making published in the FEDERAL REGISTER of October 2, 1970 (35 FR 15403), the Commissioner of Food and Drugs proposed to establish standards of identity for table sirup, maple sirup, cane sirup, and sorghum sirup.

Sixty-six persons submitted comments in response to the proposal. The respondents included members of Congress, individual consumers, members of the medical community, and representatives of the sirup industry and trade associations.

The Commissioner has considered all of the comments and has adopted the suggestions he considers to be in the interest of consumers and has made other changes. A summary of the comments and the Commissioner's responses are as follows:

1. Section 30.1(b)(1)(i) provides for the use in table sirup of maple, cane, or sorghum sirup. Although the provision for the naming of such table sirups was not misunderstood in any comment, the section has been further clarified in the final order by adding the restriction that the finished food shall not meet the requirements prescribed by the standards for maple, cane, or sorghum sirups.

2. The proposed regulation listed glucose sirup, dried glucose sirup, corn sirup, and dried corn sirup as optional ingredients in table sirup. The listing has been omitted from the final order because these ingredients are now included among the nutritive sweeteners standardized under Part 26 and are permitted as "other nutritive carbohydrate sweeteners" in § 30.1(b)(1)(iii) of the final order.

3. The proposed standard for table sirup provided for the optional use of edible fats. The Commissioner concludes that it would be in the interest of consumers to permit the use of edible oils in addition to edible fats and is providing for them. However, he is of the opinion that the use of these products in "buttered sirups" may lead the consumer to believe that butter is present in an amount greater than is actually the case. Accordingly, he concludes that edible fats and oils (other than butter) are not suitable ingredients for use in "buttered sirups." Section 30.1(b)(3) of the final order reflects this limitation.

4. One comment interpreted the proposed regulation as providing for fruit flavored sirups when used as table sirups.

It is the Commissioner's intent that such flavored sirups be permitted. Accordingly, § 30.1(b)(5) of the final order includes natural and artificial fruit flavorings among the optional ingredients. However, fruit sirups identified as such are not standardized by this final order.

5. One comment recommended that the standard for table sirup (§ 30.1) either name malic acid in addition to the examples of acidifying agents listed in the proposed regulation or give no such examples.

Section 30.1(b)(10) of the final order permits acidifying agents as a class without giving examples. (See paragraph 22 below for a further discussion of this matter.)

6. The proposed standard for table sirup also provided for "food adjuncts" among the optional ingredients. The provision has been made more explicit in § 30.1(b)(12) of the final order by replacing the term with a description of the type of ingredient intended to be included.

7. A comment asked if the name of the food can be "buttered table sirup", "buttered corn sirup", etc., when applicable.

The Commissioner advises that this is the intent of § 30.1(c). The matter has been clarified in the final order.

With respect to labeling of "buttered sirups", the current industry practice is to include a quantitative declaration of the amount of butter present. The Commissioner is of the opinion that this practice is required by the principles established in 21 CFR Part 102. Accordingly, the final order specifies that the label shall contain a statement of butter content as part of the name of the food in the manner set forth in 21 CFR Part 102.

8. Three comments suggested that the minimum size of type for designating each additional sweetening ingredient in the name of the food, when the principal sweetener constitutes at least 80 percent of the total sweetener solids, be reduced from one-half the size of the type used in the name of the principal sweetener to one-fourth the size. As an alternative, it was suggested that the portion of § 30.1(c) pertaining to type size be deleted.

It is the conclusion of the Commissioner that neither of these suggested modifications would insure adequate protection to the consumer. No information was submitted to demonstrate that consumers' interests would be served by reducing the type size requirement. It should be noted that the type size requirement is consistent with the requirements of Part 102 of this chapter. The Commissioner is not aware of any labels that are too small to accommodate the type size specified in the regulation. Accordingly, the requirement has been retained in the final order.

9. A comment asked whether the requirement in § 30.1(c), that the label designation for the additional sweetener ingredients be part of the name of the food when the principal sweetener constitutes at least 80 percent of the total sweetener solids, pertains to maple, cane, and sorghum sirups and, if so, whether such words could be shown in type size larger than one-half the height of or possibly larger than the height of the letters used in the name of the principal sweetener.

The Commissioner advises that the requirement in the proposed standard did not exclude maple, cane, or sorghum sirups nor limit the maximum size of letters in the names of the additional sweeteners. The final order prescribes that the letters be of uniform style and size not less than one-half the height of nor larger than the letters used in the name of the principal sweetener. A similar change is being made in that portion of § 30.1(c) which provides, among the alternative names for table sirup, for including in the name of the food the names of sweetening ingredients in the order that they predominate by weight in the food. The final order prescribes that the names of the sweetening ingredients be printed in type of uniform style and size.

10. A comment pointed out that the requirement in § 30.1(d)(1) for the label declaration of optional ingredients did not include all of the ingredients referenced in § 30.1(b).

As revised in the final order, the requirement pertains to all optional ingredients used. The final order also requires label declaration of all optional ingredients used in maple, cane, and sorghum sirups. The change is consistent with the provisions of 21 CFR 3.88.

11. One comment interpreted § 30.1(d)(2) to mean that maple sirup and honey must each constitute not less than 10 percent of the finished food if both maple and honey are identified as the flavors of the sirup.

The Commissioner advises that this was not the intention. The requirement has been restated in the final order to provide that the 10-percent minimum applies to the total quantity of the two ingredients.

12. Two comments suggested that § 30.1(d)(3) be changed to exempt label declaration of the percentage of any sweetening ingredient represented as furnishing a significant organoleptic contribution to the table sirup when such sweetening ingredient is mentioned only in the name of the food or in the list of ingredients.

The Commissioner concludes that this standard should incorporate the principles of 21 CFR Part 102 as they pertain to the label declaration of any characterizing ingredient (sweetening ingredient or any other) whose proportion in the food has a material bearing on price or consumer acceptance. Accordingly, the final order now requires that the percentage of any such ingredient be decared as part of the name of the food if any representation of the ingredient is made on the label other than in the list of ingredients. It is common industry practice now to include percentages in the ingredients statements on the labels of table sirups. The action being taken in this standard would not preclude a continuation of the practice.

13. Section 30.1(d) (4) and (5) of the proposal prescribed the manner for declaring artificial coloring, artificial flavoring, and chemical preservatives on the label. These subparagraphs have been omitted from the final order because their provisions are now covered by paragraph (d)(1) of § 30.1 which has been changed in the final order to require that the common name of each optional ingredient used be declared on the label as required by 21 CFR Part 1.

14. A comment recommended that the species designations, saccharum M. and nigrum Michx F. be deleted from the source of maple sap specified in § 30.2 for maple sirup and that only the genus name Acer be retained. Grounds given were that, although maple sap is primarily harvested from the Acer saccharum M. and Acer igrum Michx F. species, other species may be harvested incidentally.

The Commissioner agrees with this recommendation and the final order has been changed accordingly.

15. One comment questioned the advisability of establishing a separate standard for cane sirup.

Since a substantial amount of cane sirup is consumed as such, the Commissioner concludes a standard for that food to be in the interest of consumers.

16. The proposed standard for cane sirup designated "ribbon cane sirup" as an alternative name for "cane sirup". Since ribbon cane is only one of several varieties of sugar canes, the Commissioner concludes that not all sugar cane sirups can properly be labeled "ribbon cane sirup". It has come to the Commissioner's attention that at this time the variety of cane known as "ribbon cane" is no longer grown in the United States nor is it imported. However, in certain geographic locations cane sirup other than ribbon cane has also been incorrectly labeled as "ribbon cane sirup". The Commissioner concludes that it would not be in the interest of consumers to provide for an alternative name that would misrepresent a food. Accordingly, such alternative name is not provided for in the final order.

17. One comment requested that the use of invertase and malt diastase be permitted as processing aids in sorghum sirup.

Since such enzymes serve useful functions in the manufacture of sorghum sirup, the Commissioner has no objection to the use of these or other safe and suitable anticrystallizing and antisolidifying agents and has provided for their optional use in § 30.4(b) (4), (5), and (6) of the final order.

18. A comment requested that, as an alternative to the name of the food standardized by § 30.4, the word "sorghum", unqualified, be permitted.

Since the word "sorghum", unqualified, has been used in the trade for a long time and is accepted by the consumer as an alternative for "sorghum sirup", § 30.4(c) has been revised in the final order to provide for both names.

19. Fifty-two comments requested more informative ingredient labeling so that people who have a need or desire to know of the presence of certain substances may be so informed. Many requested that the source of ingredients be declared, for example, whether the sucrose was prepared from cane or beets.

The Commissioner agrees that it is desirable to require the declaration of all optional ingredients by their common names. At this time there are no data to support a requirement of ingredient source declaration. The issue of the significance of source labeling to those persons who may have allergic or hypersensitive reactions to specific ingredients is being reviewed at the request of the Commissioner by Life Sciences Research Office, Federation of American Societies for Experimental Biology, Bethesda, MD. If data in support of a requirement to declare the source of ingredients become available after the establishment of this regulation, the Commissioner will propose to amend the standard.

20. One comment proposed that a daily limit be established for each food chemical and that the maximum amount permitted in each sirup be a certain percentage of the total daily limit.

The Commissioner considers that the requirement of 21 CFR Part 121 that substances generally recognized as safe (GRAS) be used in accordance with good manufacturing practice and that other

substances which are food additives be used in accordance with good additive regulations precludes use of excessive amounts of food chemicals and is sufficient to protect the public health. Any limitations on the use of food ingredients for safety reasons will be imposed under the food additive provisions of the law, not under food standards.

21. One comment recommended that table sirups be fortified with minerals and vitamins.

No evidence was received which would demonstrate that the addition of minerals and vitamins to table sirups is a nutritionally sound practice or otherwise in the interest of consumers. The Commissioner has no data indicating that the addition of minerals, vitamins, and protein to this food would make a significant contribution to the diet of the population in need. On that basis, he does not consider table sirup to be a reasonable carrier for added nutrients. The principles governing the addition of nutrients to foods are presented more fully in a notice of proposed rule making to establish general principles governing the addition of nutrients to foods, published elsewhere in this issue of the FEDERAL REGISTER.

22. The Commissioner concludes that the recipe requirements of food standards should be relaxed so as to permit the use of any safe and suitable ingredients that do not adversely affect the identity of the food. Instead of listing the permitted optional ingredients by name in the standards, the final order lists them, wherever practicable, by class. Such a listing will give the manufacturer a wider selection of ingredients. Hence, it will not be necessary, in many cases, to amend the standards to permit the use of additional safe and suitable optional ingredients when such ingredients are found to serve a useful purpose.

23. Two respondents suggested that, if label changes are required, ample time be granted for producers to exhaust present inventories of labels.

A number of current changes in regulations involves significant changes in label requirements. The Commissioner is aware of the cost attending a series of changes in labeling requirements appearing over a short period of time and that in all likelihood such costs would be passed on to consumers in the form of higher food prices. Accordingly, in the interest of the consumer and the food industry, he has set January 1, 1975, as the effective date for this order.

On the basis of the proposed standards, the comments received, and other relevant information available to him, the Commissioner concludes that it will promote honesty and fair dealing in the interest of consumers to adopt the proposed standards with certain modifications as indicated.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 401, 701, 52 Stat. 1046, 1055–1056, as amended by 70 Stat. 919 and 72 Stat. 948; (21 U.S.C. 341, 371)) and under authority delegated to the Commissioner (21 CFR 2.120): *It is ordered*, That Chapter I of Title 21, Code of Federal Regulations be amended by adding a new Part 30 as follows:

Sec.
30.1 Table sirup; identity; label statement of optional ingredients.
30.2 Maple sirup; identity; label statement of optional ingredients.
30.3 Cane sirup; identity; label statement of optional ingredients.
30.4 Sorghum sirup; identity; label statement of optional ingredients.

AUTHORITY: Secs. 401, 701, 52 Stat. 1046, 1055–1056, as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 341, 371).

§ 30.1 Table sirup; identity; label statement of optional ingredients.

(a) Table sirup is the liquid food consisting of one or more of the optional sweetening ingredients provided for in paragraph (b)(1) of this section. The food contains not less than 65 percent soluble sweetener solids by weight and is prepared with or without added water. It may contain one or more of the optional ingredients prescribed in paragraphs (b) (2) through (12) of this section. All ingredients from which the food is fabricated shall be safe and suitable. (Vitamins, minerals, and protein added for nutritional purposes and artificial sweeteners are not considered to be suitable ingredients for this food.)

(b) The optional ingredients that may be used in table sirup are:

(1) One or more of the nutritive carbohydrate sweeteners provided for in this paragraph (b)(1). When a sweetener provided for in paragraph (b)(1) (i) or (ii) of this section is used it shall constitute not less than 2 percent by weight of the finished food.

(i) The sirups identified by §§ 30.2, 30.3, and 30.4 except that the use of any such ingredient is so limited that the finished food does not meet the requirement prescribed for any sirup by §§ 30.2, 30.3, or 30.4.

(ii) Honey.

(iii) Other nutritive carbohydrate sweeteners.

(2) Butter, in an quantity not less than 2 percent by weight of the finished food.

(3) Edible fats and oils, except that, in products designated as "buttered sirups", butter as provided for in paragraph (b)(2) of this section is the only fat that may be used.

(4) Emulsifiers or stabilizers or both.

(5) Natural and artificial flavorings, either fruit or nonfruit, alone or in carriers.

(6) Color additives.

(7) Salt.

(8) Chemical preservatives.

(9) Viscosity adjusting agents.

(10) Acidifying, alkalizing, or buffering agents.

(11) Defoaming agents.

(12) Any other ingredient (e.g., shredded coconut, ground orange peel) that is not incompatible with other ingredients in the food.

(c) Except as provided for in this paragraph and in paragraph (d) (2) and (3) of this section, the name of the food is "table sirup", "sirup", "pancake sirup", "waffle sirup", "pancake and waffle sirup", or "_____ sirup", the blank being filled in with the word or words that designate the sweetening ingredient that characterizes the food, except "maple", "cane", or "sorghum" alone, such sirups being required to comply in all respects with §§ 30.2, 30.3, and 30.4, respectively, and in the case of more than one sweetening ingredient, in descending order of predominance by weight in the food. The type shall be of uniform style and size.

(1) When one of the sweeteners constitutes at least 80 percent of the total sweetener solids, the name of the food may be designated as the corresponding sirup, for example, "corn sirup", provided that the name is immediately and conspicuously followed, without intervening written, printed, or graphic matter, by the statement "with _____" as part of the name, the blank being filled in with the name or names of each additional sweetening ingredient present, stated in a clear legible manner in letters of uniform style and size not less than one-half the height of, nor larger than, the letters used in the name of the principal sweetener.

(2) When butter is used, as provided for in paragraph (b)(2) of this section, the name of the food may be "buttered _____", the blank being filled in with the name otherwise prescribed in this paragraph. The percentage by weight of butter present shall be declared as part of the name of the food as prescribed by Part 102 of this chapter.

(3) Alternatively, the word "sirup" may be spelled "syrup".

(d) (1) Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 1 of this chapter.

(2) A statement (other than in the ingredient listing) or a vignette identifying a flavor may be included on the label only if such flavor contributes the primary recognizable flavor that characterizes the sirup. When maple, honey, or both maple and honey are represented as the characterizing flavors, the total quantity of maple sirup or honey, singly, or of maple sirup and honey in combination, shall be not less than 10 percent by weight of the finished food. The presence of any natural or artificial flavor in the food shall be declared on the label as prescribed by the applicable sections of Part 1 of this chapter.

(3) The percentage of any optional ingredient used shall be declared as part of the name of the food as prescribed by Part 102 of this chapter when all of the following conditions apply to the use of the ingredient:

(i) It is one of the characterizing ingredients permitted by paragraph (b)(1)(i) and (ii) of this section.

(ii) The ingredient is either named on the label other than in the list of ingredients or is suggested by vignette or other labeling.

§ 30.2 Maple sirup; identity; label statement of optional ingredients.

(a) Maple sirup is the liquid food derived by concentration and heat treatment of the sap of the maple tree (Acer) or by solution in water of maple sugar (maple concrete) made from such sap. It contains not less than 66 percent by weight of soluble solids derived solely from such sap. The concentration may be adjusted with or without added water. It may contain one or more of the optional ingredients provided for in paragraph (b) of this section. All ingredients from which the food is fabricated shall be safe and suitable.

(b) The optional ingredients that may be used in maple sirup are:

(1) Salt.
(2) Chemical preservatives.
(3) Defoaming agents.

(c) The name of the food is "maple sirup". Alternatively, the word "sirup" may be spelled "syrup".

(d) Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 1 of this chapter.

§ 30.3 Cane sirup; identity; label statement of optional ingredients.

(a) Cane sirup is the liquid food derived by concentration and heat treatment of the juice of sugarcane (Saccharum officinarum L.) or by solution in water of sugarcane concrete made from such juice. It contains not less than 74 percent by weight of soluble solids derived solely from such juice. The concentration may be adjusted with or without added water. It may contain one or more of the optional ingredients provided for in paragraph (b) of this section. All ingredients from which the food is fabricated shall be safe and suitable.

(b) The optional ingredients that may be used in cane sirup are:

(1) Salt.
(2) Preservatives.
(3) Defoaming agents.

(c) The name of the food is "cane sirup". Alternatively, the word "sirup" may be spelled "syrup".

(d) Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 1 of this chapter.

§ 30.4 Sorghum sirup; identity; label statement of optional ingredients.

(a) Sorghum sirup is the liquid food derived by concentration and heat treatment of the juice of sorghum cane (sorgos) (Sorghum vulgare). It contains not less than 74 percent by weight of soluble solids derived solely from such juice. The concentration may be adjusted with or without added water. It may contain one or more of the optional ingredients provided for in paragraph (b) of this section. All ingredients from which the food is fabricated shall be safe and suitable.

(b) The optional ingredients that may be used in sorghum sirup are:

(1) Salt.
(2) Chemical preservatives.
(3) Defoaming agents.
(4) Enzymes.
(5) Anticrystallizing agents.
(6) Antisolidifying agents.

(c) The name of the food is "sorghum sirup" or "sorghum". Alternatively, the word "sirup" may be spelled "syrup".

(d) Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 1 of this chapter.

Any person who will be adversely affected by the foregoing order may at any time on or before July 15, 1974, file with the Hearing Clerk, Food and Drug Administration, Room 6–86, 5600 Fishers Lane, Rockville, MD 20852, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the order, specify with particularity the provisions of the order deemed objectionable, and state the grounds for the objections. If a hearing is requested, the objections shall state the issues for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Objections may be accompanied by a memorandum or brief in support thereof. Six copies of all documents shall be filed. Received objections may be seen in the above office during working hours, Monday through Friday.

Effective date. Compliance with this order shall begin on January 1, 1975, except as to any provisions that may be stayed by the filing of proper objections. Notice of the filing of objections or lack thereof will be published in the FEDERAL REGISTER.

(Secs. 401, 701, 52 Stat. 1046, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 341, 371))

Dated: June 7, 1974.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.74–13481 Filed 6–13–74;8:45 am]

PART 53—TOMATO PRODUCTS

Tomato Juice; Amendment of Identity Standard

In the FEDERAL REGISTER of March 25, 1974 (39 FR 11095), the Commissioner of Food and Drugs issued a proposal submitted by Del Monte Corp., 215 Fremont St., P.O. Box 3575, San Francisco, CA 94119, to amend the tomato juice identity standard (21 CFR 53.1) to provide for the optional use of ascorbic acid (vitamin C) in such quantity that the total vitamin C in each 6 fluid ounces of finished food amounts to 100 percent of the U.S. Recommended Daily Allowance (U.S. RDA) for vitamin C.

A total of 21 comments was received in response to the proposal. Eight consumers, a tomato juice manufacturer, an ingredient manufacturer, and a State official favored the proposal while five consumers, a tomato juice manufacturer, a citrus growers' association, a supermarket chain, and a professor of nutritional physiology opposed the proposal. One fruit juice beverage manufacturer favored the addition of vitamin C to tomato juice with qualifications. The points raised by the comments and the Commissioner's conclusions are as follows:

1. The five consumers who opposed the addition of vitamin C to tomato juice commented that (a) such a change would deprive the public of an opportunity to purchase and consume tomato juice which does not contain added vitamin C, (b) they prefer to have their tomato juice in its natural state, and (c) the addition of vitamin C would add to the cost of the tomato juice.

The Commissioner points out that the proposal does not require a manufacturer of tomato juice to add vitamin C but provides him with the choice of either adding it or not adding it. Consumers would therefore have freedom of choice between a vitamin C fortified or nonfortified product in the marketplace. It is estimated that the cost of the additive alone when purchased in bulk quantities is less than $\frac{1}{10}$ cent per 60 milligrams, the amount which would be used to fortify a 6 fluid-ounce serving. Consequently, the amount of ascorbic acid that would be added to tomato juice should not materially affect the cost of the product.

2. The Citrus Growers Association opposed the proposal on the grounds that (a) the petitioner wishes to fortify tomato juice for strictly competitive reasons and to gain a bigger share of the juice market and (b) this share is partially gained by the use of an added substance which is naturally present in the same amount in orange juice.

The Commissioner concludes that, while the market availability of a tomato juice product containing an amount of vitamin C equivalent to orange juice presents competition to the producers of orange juice, this is not a proper factor to consider in determining whether the product should be enriched with vitamin C. The Commissioner's decision on this matter is based solely upon determinations relating to public health and nutrition. Tomato juice is used primarily as a breakfast beverage. Breakfast beverages constitute the major source of vitamin C in the daily diet of most people. The "USDA Household Food Consumption Survey 1965–1966" indicates that only about 30 to 58 percent of the recommended dietary allowance of vitamin C is obtained from all other food sources combined. It is therefore important from the standpoint of public health and nutrition that all foods of this class be interchangeable in terms of this important nutrient.

The Commissioner had earlier contracted with the National Academy of Sciences/National Research Council for assistance in identifying and defining the important classes of foods for which nutritional quality guidelines should be established and in providing proposed

nutrient compositions for them which would be in the best interest of the public health. The recommendations of the Committee on Food Standards and Fortification Policy of the National Academy of Sciences/National Research Council (the NAS/NRC Committee) for ascorbic acid fortified vegetable juices, fruit juices, fruit drinks, and imitation fruit-flavored drinks reflect the fact that some conventional vegetable and fruit juices are major sources of vitamin C in the diet, and that other such products which are not naturally good sources of the vitamin, and many flavored beverages, have been fortified with vitamin C at various levels. The recommendations are intended to assure the consumer that when vitamin C is added to such a product, it will provide a nutritionally adequate level of the vitamin but will not be in excess of nutritional requirements. The NAS/NRC Committee recommended a minimum supplement level of 50 mg per 6 fluid-ounce serving (or equivalent) and a maximum supplement level of 65 mg per 6 fluid-ounce serving (or equivalent). These values represent the mean Recommended Daily Allowance and an average ascorbic acid content of citrus juices, respectively. However, in a proposal to establish nutritional quality guidelines for breakfast beverage products published elsewhere in this issue of the FEDERAL REGISTER, the Commissioner is of the opinion that one level, consistent with the newly established U.S. RDA (60 mg), should be proposed. The Commissioner is also of the opinion that there is no justification for establishing an upper limit beyond 60 mg per average serving (6 fl. oz.) since this level of fortification is essentially the same as occurs naturally in various citrus juices, which are among the richest sources of the vitamin, and since there is no known nutritional significance to supplemental intakes beyond this level. A copy of the NAS/NRC Committee report is on public display in the office of the Hearing Clerk.

3. The Citrus Growers Association commented that the citrus industry is supporting medical research on the physiological value of naturally occurring vitamin C, and that it expects the data to show an increased benefit over ascorbic acid, the form of the vitamin proposed for addition. On the basis of this expectation, the Association believes that "vitamin C," when added as ascorbic acid, should be described in labeling as "synthetic" or should be exclusively termed "ascorbic acid."

The Association's contention that there may be a difference in biological value activity between naturally occurring vitamin C and ascorbic acid is not supported by scientific evidence at this time. It is noted that finding of fact number 26, relating to the public hearings on foods for special dietary use, published in the FEDERAL REGISTER of August 2, 1973 (38 FR 20708) states "there is no nutritional difference between a vitamin provided by a synthetic source and the same vitamin provided by a natural source, but the natural source may contain other ingredients which may limit the absorbability of the vitamin provided by the natural source." Consequently, until it can be demonstrated by reliable scientific data that there is a nutritional difference between added ascorbic acid and ascorbic acid occurring naturally in orange juice, the Commissioner has no reason to require that products containing the former be labeled differently from those containing the naturally occurring form of the vitamin.

4. The supermarket food chain opposed the proposal on the ground that the indiscriminate fortification of natural foods will inevitably lead to a numbers race with products being fortified to meet the nutrient level of another product for no good reason.

Although the Food and Drug Administration has not proposed nutritional quality guidelines for all foods, it has established general principles for setting such guidelines for classes of foods (21 CFR 100.1). Elsewhere in this issue of the FEDERAL REGISTER, the Commissioner is proposing amendments to the nutrition guideline regulations which set forth in detail the circumstances under which nutrients may be added to foods. This final order meets the principles contained in that proposal.

The Commissioner concludes that, in view of the NAS/NRC Committee recommendation for addition of ascorbic acid to vegetable juices, fruit juices, fruit drinks and imitation fruit-flavored drinks, it would not be reasonable to prohibit a food which is a natural source of vitamin C from further enrichment to provide a nutritionally adequate amount of the vitamin per serving. The Commissioner also notes that the present nutrition labeling regulations (21 CFR 1.17 and 80.1) include provisions that set maximum limits which may be claimed for added nutrients as well as permit only the use of nutrients which have been shown to be essential to human nutrition.

5. The comment from the nutritional physiologist stated that, whereas he is in favor of tomato juice assuring a given quantity of vitamin C, it is difficult to justify on the basis of citrus products or breakfast use the addition of vitamin C at 100 percent of the U.S. RDA. He commented that tomato juice is as important a source of vitamin A as it is vitamin C, and suggested that the vitamin A level as well as other nutrients normally found in tomato juice at levels greater than 2 percent U.S. RDA should be restored.

The Commissioner concludes that the high level of vitamin C is justified for the reasons set forth above. The question of restoring all nutrients in tomato juice to their natural levels is a concept that would entail considerable study and goes beyond the scope of the published proposal. Vitamin A is available naturally and as an added nutrient in a much greater variety of foods than is vitamin C. Consequently, consumers may satisfy their required daily intake of vitamin A more readily than such intake of vitamin C.

6. The fruit juice beverage manufacturer that endorsed the proposal with a qualification expressed concern that the proposed amendment in question, if promulgated, would result in further discrimination against processors of other standardized and nonstandardized beverages which are now prohibited from adding a similar quantity of vitamin C by reason of the provisions of 21 CFR 80.1.

The Commissioner points out that paragraph (b) of the final order sets forth the requirement that tomato juice shall be labeled in accordance with the applicable sections of 21 CFR Part 1. Consequently, if vitamin C is added to the tomato juice, the food is subject to the same labeling requirements of 21 CFR 1.17 that a nonstandardized food would be if it contained vitamin C in the same quantity as proposed in this amendment. The proposal to establish a nutritional quality guideline for breakfast beverages, published elsewhere in this issue of the FEDERAL REGISTER, proposes an exemption for breakfast beverage products from the restriction in 21 CFR 1.17 limiting the addition of vitamin C to less than 50 percent of the U.S. RDA per serving. Therefore, the Commissioner cannot agree that this proposal will discriminate against processors of other standardized and nonstandardized foods.

7. The proposal stated that the ascorbic acid may be added in such a quantity that the total vitamin C in each 6 fluid-ounce serving of the finished food amounts to 10 percent of the U.S. RDA for vitamin C (60 mg). In order to use language consistent with that set forth in the proposal to establish a nutritional quality guideline for breakfast beverage products, the Commissioner has revised the vitamin C statement above to read: "* * * the total vitamin C in each fluid ounce of the finished food is 10 milligrams * * *." This is an editorial revision and does not change the proposal in regard to the amount of ascorbic acid that may be added to tomato juice.

8. It was brought to the Commissioner's attention that the proposal failed to provide for a method of analysis for determining the amount of ascorbic acid present in tomato juice.

This was an oversight and such a method has been included in this document.

9. Elsewhere in this issue of the FEDERAL REGISTER, the Commissioner is proposing general principles for the addition of nutrients to foods wherein the terms "fortified" and "enriched" are defined. That proposal specifics that no label claims regarding added nutrients will be permitted unless such addition(s) constitutes at least 10 percent of the U.S. RDA for the nutrient(s). For tomato juice which conforms to the standard and is "enriched" according to the definition contained in that proposal; use of

the statement "enriched with vitamin C" is proper when vitamin C is added at levels prescribed by the standard.

Accordingly, after careful consideration of the comments received, the information submitted by the petitioner, and other relevant information, including the recommendations submitted under contract to the Food and Drug Administration by the Committee on Food Standards and Fortification Policy, Food and Nutrition Board of the National Academy of Sciences/National Research Council, the Commissioner concludes that it will promote honesty and fair dealing in the interest of consumers to amend the standard of identity for tomato juice (21 CFR 53.1) to provide for the optional addition of ascorbic acid (vitamin C) in a quantity such that the total vitamin C in each fluid ounce of the finished food is 10 milligrams.

Therfore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 401, 701, 52 Stat. 1046, 1055 as amended by 70 Stat. 919 and 72 Stat. 948; 21 U.S.C. 341, 371) and under authority delegated to the Commissioner (21 CFR 2.120): *It is ordered*, That Part 53 be amended by revising § 53.1 to read as follows:

§ 53.1 Tomato juice; identity; label statement of optional ingredients.

(a) Tomato juice is the unconcentrated liquid extracted from mature tomatoes of red or reddish varieties, with or without scalding followed by draining. In the extraction of such liquid, heat may be applied by any method which does not add water thereto. Such liquid is strained free from skins, seeds, and other coarse or hard substances, but carries finely divided insoluble solids from the flesh of the tomato. Such liquid may be homogenized, and may be seasoned with salt. Such liquid may contain added ascorbic acid in a quantity such that the total vitamin C in each fluid once of the finished food is 10 milligrams as determined by the method prescribed in sections 39.051–39.055 of the Official Methods of Analysis of the Association of Official Analytical Chemists, 11th ed., 1970, pp. 777–778, under "Vitamin C (Ascorbic Acid) Official Final Action".[1]

When sealed in a container it is so processed by heat, before or after sealing, as to prevent spoilage.

(b) Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 1 of this chapter. Tomato juice to which vitamin C has been added may bear on its label the statement "Enriched with Vitamin C" in accordance with § 100.1 of this chapter or "with added vitamin C" or a similar statement.

Any person who will be adversely affected by the foregoing order may at any time on or before July 15, 1974, file with the Hearing Clerk, Food and Drug Administration, Rm. 6–86, 5600 Fishers Lane, Rockville, MD 20852, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the order, specify with particularity the provisions of the order deemed objectionable, and state the grounds for the objections. If a hearing is requested, the objections shall state the issues for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Objections may be accompanied by a memorandum or brief in support thereof. Six copies of all documents shall be filed. Received objections may be seen in the above office during working hours, Monday through Friday.

[1] Copies may be obtained from: The Association of Official Analytical Chemists, Box 540, Benjamin Franklin Station, Washington, DC 20004.

Effective date. This order shall become effective August 13, 1974, except as to any provisions that may be stayed by the filing of proper objections. Notice of the filing of objections or lack thereof will be given by publication in the FEDERAL REGISTER.

(Secs. 401, 701, 52 Stat. 1046, 1055–1056, as amended by 70 Stat. 919 and 72 Stat. 948; (21 U.S.C. 341, 371))

Dated: June 7, 1974.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.74–13483 Filed 6–13–74;8:45 am]

PART 125—LABEL STATEMENTS CONCERNING DIETARY PROPERTIES OF FOOD PURPORTING TO BE OR REPRESENTED FOR SPECIAL DIETARY USES

Use of International Units for Vitamins A and D; Confirmation of Effective Date of Order

In the FEDERAL REGISTER of February 12, 1974 (39 FR 5313), a final order was published which amended § 125.5(c)(5) (21 CFR 125.5(c)(5)) of Part 125 by inserting "International Units" in place of "U.S.P. Units" as the units of measurement for vitamins A and D. The order provided for the filing of objections on or before March 14, 1974.

Pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 403, 701, 52 Stat., 1047–1048, 1055–1056, as amended; 21 U.S.C. 343, 371) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120), notice is given that no objections to the order were filed. Therefore, the amendment promulgated by the subject order became effective on March 14, 1974.

Dated: June 7, 1974.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.74–13482 Filed 6–13–74;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Parts 1, 3]

MULTIUNIT AND MULTICOMPONENT FOOD PACKAGES

Proposed Exemptions From Required Label Statements

The Commissioner has received a petition from The National Association of Margarine Manufcturers requesting that the labeling of ingredients on the wrapper of a subdivision of oleomargarine or margarine be optional when such subdivision does not constitute a separate unit for retail sale.

The petition is available for inspection in the office of the Hearing Clerk, Food and Drug Administration, Rm. 6–86, 5600 Fishers Lane, Rockville, MD 20852.

The Commissioner has considered the petition and agrees that an exemption from label requirements for a statement of ingredients should be granted for the wrapper on a subdivision of oleomargarine or margarine where the subdivision does not constitute a separate unit of retail sale. However, the Commissioner recognizes that such an exemption should also apply to other foods packaged in a like manner, including foods in multicomponent retail packages and other multiunit retail packages.

Accordingly, by amending § 1.1c (21 CFR 1.1c), the Commissioner proposes to exempt unit containers in a multiunit or multicomponent retail food package from the requirement for label declaration of ingredients, provided that the outside of the retail package is properly labeled and the unit containers do not constitute separate units for retail sale. Similarly, it is proposed that § 3.17(i) (21 CFR 3.17(i)) be amended to conform with § 1.1c and to exempt the wrappers on the subdivisions of oleomargarine or margarine contained within the packages sold at retail from the requirement for label declaration of ingredients, provided the packages sold at retail are properly labeled and the subdivisions do not constitute separate units for retail sale. Since reference to special dietary use was deleted from § 45.1(b)(2)(v) in an order published in the FEDERAL REGISTER of March 14, 1973 (38 FR 6968), the same reference is being deleted from the proposed revision of § 3.17(d) and (i).

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 403, 407, 701(a), 52 Stat. 1047–1048, 1055, 64 Stat. 20; 21 U.S.C. 343, 347, 371(a)) and under authority delegated to him (21 CFR 2.120), the Commissioner proposes that Chapter I of Title 21, Code of Federal Regulations be amended as follows:

1. In Part 1 by adding new paragraph (a)(14) to § 1.1c as follows:

§ 1.1c Exemptions from required label statements.

* * * * *

(a) * * *

(14) The unit containers in a multiunit or multicomponent retail food package shall be exempt from compliance with the requirements of section 403 (g)(2), (i)(2), and (k) of the act with respect to the requirements for label declaration of ingredients when the multiunit or multicomponent retail food package labeling meets all the requirements of this part and the unit containers are securely enclosed within and not intended to be separated from the retail package under conditions of retail sale.

* * * * *

2. In Part 3 by revising paragraphs (d) and (i) of § 3.17 to read as follows:

§ 3.17 Labeling of oleomargarine or margarine.

* * * * *

(d) All oleomargarine or margarine containing the optional ingredients vitamin A, vitamin D, or both is subject to the provisions of § 1.17 of this chapter.

* * * * *

(i) The wrappers on the subdivisions of oleomargarine or margarine contained within the package sold at retail are labels within the meaning of section 201 (k) and shall contain all of the label information required by sections 403 and 407 of the Federal Food, Drug and Cosmetic Act, just as in the case of 1-pound cartons, except that wrappers on the subdivisions contained within the retail package shall be exempt from the requirement for label declaration of ingredients when the subdivisions are securely enclosed within and are not intended to be separated from the retail package under conditions of retail sale.

Interested persons may, on or before August 13, 1974, file with the Hearing Clerk, Food and Drug Administration, Rm. 6–86, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding the petition and the Commissioner's proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: June 7, 1974.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.74–13477 Filed 6–13–74;8:45 am]

[21 CFR Parts 1, 10, 102]

UNIFORM METHOD OF DECLARING THE PERCENTAGE OF AN INGREDIENT IN FOODS

Proposed Percentage Labeling Requirements

The Commissioner of Food and Drugs has received a petition submitted on behalf of Giant Foods, Inc., proposing to amend 21 CFR 102.1 to provide a uniform system of percentage ingredient labeling of a product whenever percentage ingredient labeling is used. The statement of grounds and the requested revision of § 102.1 are as follows:

Giant Foods, a Washington-based grocery chain, is concerned with the right and ability of the consumer to be informed about the food products that are purchased. In 1971, a committee of consumer and industry representatives was organized to consider a percentage ingredient labeling program and as a result of the committee's efforts, Giant Food has voluntarily begun to label eight of its own brand products with percentage information.

Giant Foods would like to proceed with this program and to give the consumer percentage information on a greater variety of its own products. However, Giant is concerned that the Food and Drug Administration regulations on percentage labeling are being promulgated on a product-by-product basis. Waiting for common or usual names to be promulgated by the Food and Drug Administration, Giant has not been able to move ahead with their program in fear that the FDA might later propose regulations that would make their new labels obsolete.

Giant Foods proposes that in the interest of consumers, percentage labeling requirements should be on a voluntary/mandatory system analogous to the present nutrition labeling program. Consequently, Giant Foods respectfully proposes, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 403 and 701(a)), that regulations establishing requirements for the promulgation of common or usual names and mandatory/voluntary percentage of ingredient labeling be adopted by the Food and Drug Administration in the following format:

§ 102.1a Common or usual names for nonstandardized foods.

(a) The common or usual name of a food, which may be a coined term shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients. The name shall be uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name. Each class or subclass of food shall be given its own common or usual name that states, in clear terms, what it is in a way that distinguishes it from different foods.

(b) The common or usual name of a food shall include the percentage(s) of any characterizing ingredient(s) or component(s) when the proportion of such ingredient(s) or component(s) in the food has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present in an amount greater than is actually the case, the requirements of § 102.1(b) shall apply.

(c) A common or usual name of a food may be established by common usage or by establishment of a regulation in Subpart B of this part, in Part 100, in a standard of identity, or in other regulations in this chapter.

§ 102.1b Percentage ingredient labeling.

(a) Percentage ingredient labeling relating to any food may be included on the label and in the labeling of a product: *Provided*, That it conforms to the requirements of this section. Except, whenever the Secretary promulgates a common or usual name for a product, such product will be required to contain percentage ingredient labeling in accordance with the requirements of this section.

(b) The percentage of a characterizing ingredient of component shall be declared on

the basis of its quantity in the finished product (i.e., weight/weight in the case of solids, or volume/volume in the case of liquids.)

(c) A characterizing ingredient is any component of a food product (1) in which the proportion in the food has a material bearing on the price or consumer acceptance, (2) which a consumer might otherwise believe to be present in an amount greater than is actually the case, or (3) which is stated or implied in the name of the food. A characterizing ingredient does not include flavorings which must be declared in accordance with the provisions of § 1.12 of this chapter.

The declaration of the percentage of a characterizing ingredient must accurately express the amount of the ingredient contained in the food. Reasonable excesses over labeled amounts are acceptable within the limits of good manufacturing practice.

(d) The percentage of each characterizing ingredient or component shall be declared by the words "containing (or contains) ____ percent (or %) ____" or "____ percent (or %) ____" with the first blank filled in with the percentage expressed as a whole number not greater than the actual percentage of the ingredient or component named and the second blank filled in with the common or usual name of the ingredient or component. The word "containing" (or "contains"), when used, shall appear on a line immediately below the name of the food in easily legible boldface print or type in distinct contrast to other printed or graphic matter, and in a height not less than the larger of the following alternatives:

(1) Not less than one-sixteenth inch in height on packages having a principal display panel with an area of 5 square inches or less and not less than one-eighth inch in height if the area of the principal display panel is greater than 5 square inches; or

(2) Not less than one-half the height of the largest type appearing in the part of the common or usual name of the food required by paragraph (a) of this section.

(e) Percentage ingredient labeling shall include a statement of the presence or absence of any characterizing ingredient(s) or component(s) and/or the need for the user to add any characterizing ingredient(s) or component(s) when the presence or absence of such ingredient(s) or component(s) in the food has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present when it is not, and consumers may otherwise be misled about the presence or absence of the ingredient(s) or component(s) in the food. The following requirements shall apply:

(1) The presence or absence of a characterizing ingredient or component shall be declared by the words "containing (or contains) ____", "containing (or contains) no ____" or "no ____", or "does not contain ____", with the blank being filled in with the common or usual name of the ingredient or component.

(2) The need for the user of a food to add any characterizing ingredient(s) or component(s) shall be declared by an appropriate informative statement.

(3) The statement(s) required under paragraph (e) (1) and/or (2) of this section shall appear following or directly below the part of the name of the food in easily legible boldface print or type in distinct contrast to other printed or graphic matter, and in a height not less than the larger of the alternatives established under paragraph (d) (1) and (2) of this section.

(f) A label which contains percentage of ingredient listings in accordance with this regulation shall list on the label in descending order of their predominance all of the ingredients contained in the product.

(1) Whenever a percentage of ingredient listing appears on the main display panel, that percentage shall also be listed in parentheses following the ingredient name on the full ingredient list.

(2) The percentages of any of the ingredients other than the characterizing ingredient(s) may be listed in parentheses following the name of the ingredients on the full ingredient list.

(g) If the principal display panel of a food is too small to accommodate all mandatory requirements of this section, the Commissioner may establish by regulation an acceptable alternative for placement of the required information, (e.g., a smaller type size). A petition requesting such a regulation, which would amend the applicable regulation, shall be submitted to the office of the Hearing Clerk in the form set forth in § 2.65 of this chapter.

The Commissioner is in basic agreement with the suggestion that a uniform method of declaring the percentage of characterizing ingredients and other ingredients in a food would be helpful to consumers by preventing confusion and deception that could be engendered by the use of various different methods of declaration on different food labels. A uniform label placement of percentage declaration would also be helpful to the food industry by assuring that such declaration will be regarded as proper. This does not, however, preclude the possibility of establishing a regulation under Part 102 at some time in the future which would set forth other requirements for a specific food.

The Commissioner proposes to accomplish the objectives of the petition by modification of existing regulations but not as proposed by the petitioner. These modifications would establish the manner in which the percentage declaration of an ingredient will be placed in the ingredient statement when such declaration is used, and would require percentage declaration as part of the common or usual name of the food if such percentage declaration is used other than in the ingredient statement. These regulations will also be applicable to standardized foods if a percentage declaration is given that is not required by an applicable standard or is used in advertising or promoting a standardized food.

The proposed regulation provides only for the voluntary placement of percentage declaration on the label and is intended to pertain only to the percentage of the ingredient contained in the food as purchased by the consumer or, in the case of foods that must be reconstituted before use, on the basis of the percentage in the reconstituted food (i.e., weight/weight in the case of solids, or volume/volume in the case of liquids). It is apparent that if any other basis is used it would be necessary to qualify the percentage declaration explaining the basis used in its determination in order for the percentage declaration to be meaningful, fully informative, and useful for value comparison of products.

Since the proposed regulation does not specify requirements for the basis of expressing percentage declaration on the label, it is entirely possible that such declaration without qualification would be misleading or deceptive to the consumer. For example, the percentage of a dried ingredient used in a product that is sold to the consumer for use as a soup or other food that is not dried when consumed could be included in the ingredient statement on the basis of the formula weight of the dried ingredient, or on the rehydrated formula weight of the ingredient. Further, the weight of the food used in the percentage declaration could be expressed in terms of the formula, the finished food, or some food that the consumer prepares from the product purchased. The proposed regulation does not prohibit any of the possibilities for expressing the percentage declaration providing it is truthful and not misleading.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201, 401, 403, 701, 52 Stat. 1041 as amended, 1046–1048, 1055 as amended; 21 U.S.C. 321, 341, 343, 371) and under authority delegated to him (21 CFR 2.120), the Commissioner proposes to amend Chapter I of Title 21 of the Code of Federal Regulations as follows:

PART 1—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND THE FAIR PACKAGING AND LABELING ACT

1. By adding the following sentences to the end of § 1.10(e):

§ 1.10 Food; labeling; designation of ingredients.

* * * * *

(e) * * * If the percentage of any ingredient is included in the statement of ingredients, it shall be shown in parentheses following the name of the ingredient. When a percentage declaration is included in the ingredient statement, it shall not be misleading and shall be truthful in all respects.

PART 10—DEFINITIONS AND STANDARDS FOR FOOD

2. By adding the following new section to Part 10:

§ 10.8 Voluntary listing of percentage of ingredients of standardized foods.

(a) When the label of a standardized food is not required by the applicable standard to bear a percentage declaration of one or more ingredients in a statement of ingredients but does bear such a declaration, the percentage declaration shall be stated in accordance with the requirements of § 1.10(e) of this chapter.

(b) When the label or labeling or advertising of a standardized food bears a declaration of the percentage of a characterizing ingredient, other than in the ingredient statement as provided for in paragraph (a) of this section, and such declaration is not required by the applicable standard, such percentage declaration shall be declared in the manner set forth in § 102.1(b) of this chapter.

PART 102—COMMON OR USUAL NAMES FOR NONSTANDARDIZED FOODS

3. By adding the following new paragraph (b)(3) to § 102.1:

§ 102.1 General principles.

* * * * * * *

(b) * * *

(3) When the percentage of a characterizing ingredient is stated on the label or in labeling or advertising, other than as a percentage of a particular ingredient in a complete statement of ingredients as provided in § 1.10(e) and § 10.8(a) of this chapter, it shall be declared on the label as part of the common or usual name of the food in accordance with the provisions of this paragraph.

* * * * * * *

Interested persons may, on or before August 13, 1974, file with the Hearing Clerk, Food and Drug Administration, Room 6–86, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: June 7, 1974.

A. M. SCHMIDT,

Commissioner of Food and Drugs.

[FR Doc.74–13468 Filed 6–3–74;8:45 am]

[21 CFR Parts 1, 101]

NUTRITION LABELING

Proposed Serving and Portion Sizes and Daily Consumption Amounts

Section 1.17(b) of this chapter (21 CFR 1.17(b)) requires that nutrition information in the labeling of a food be declared in relation to the average or usual serving or, where the food is customarily not consumed directly, in relation to the average or usual portion. Nutrition information may also be declared on the basis of the amount of the food consumed on a daily basis.

In the preamble to the nutrition labeling regulation published in the FEDERAL REGISTER of January 19, 1973 (38 FR 2125, 2130), the Commissioner of Food and Drugs stated, "Where there are no established reasonable standard serving sizes, the Commissioner intends establishing such reasonable standard serving sizes." Subsequently, he advised in paragraph 17 of the preamble to the revision of that regulation, published in the FEDERAL REGISTER of March 14, 1973 (38 FR 6953), that " * * * it is incumbent upon industry and consumers to work together to devise uniform serving and portion sizes." The Commissioner stated, "If this does not materialize, the Commissioner will establish a procedure for adopting uniform serving and portion sizes that will be applicable to all foods."

Uniform and reasonable serving sizes are essential since nutrition labeling statements based on unreasonably large quantities per serving give an inflated idea of nutrient content and confuse consumers, and lack of uniform serving sizes among products in the same class of food makes comparison impossible. A recent survey of current product labels providing nutrition information conducted by the Food and Drug Administration demonstrates, however, that the serving and portion sizes used are in many cases not reasonable or not uniform within a product class.

In some cases the reasonableness of the serving size being used is dubious because it is larger than the serving size recommended prior to use of nutrition labeling. Since a larger serving size permits declaration of more nutrients, there is an obvious temptation to increase it. While a diversity of serving sizes exists in the marketplace, the Commissioner is aware that there is an effort to establish the serving size for canned vegetables, such as green beans, peas, and tomatoes, at 1 cup (8 ounces). For many years prior to nutrition labeling, the standard serving size usually used in labeling was ½ cup. Comments are now being received from consumers and dietitians that this is larger than the amount that would normally be consumed by an individual. Prior to nutrition labeling, the recommendation was 4 servings per pound or 3–4 servings for a pound or 1.1-pound package. Thus, the recommended serving has approximately doubled in size since the advent of nutrition labeling.

The same serving enlargement is seen in the labeling of canned fruit. Prior to nutrition labeling, canned fruit, such as pears and peaches, was labeled as containing 3–4 servings per 1- or 1.1-pound can, or in at least one instance, 5–7 servings in a can containing 1 pound, 14 ounces. Now the serving seems generally to be 1 cup (8 ounces), again an approximate doubling of the serving size. Here again, comments are being received that this is an unrealistically large amount for individual consumption.

Fruit juice has experienced a similar increase in suggested serving size. Prior to nutrition labeling, the recommended serving was customarily 6 ounces. Labels of fruit drink using nutrition labeling now generally use an 8-ounce serving. In contrast, the serving size of some brands of orange drink is presently 4 ounces.

The survey disclosed that labels on other products are suggesting serving sizes that seem to be unreasonably large. One brand of frozen peas establishes a serving of 6⅔ ounces for the purposes of nutrition information, providing 1½ servings per package, and, as if to concede the excessive size of the stated serving, also indicates that there are four 2½-ounce servings in the package. A different brand of frozen peas and carrot points in cream sauce establishes an 8-ounce serving for nutrition labeling but adds that the package also provides four 2½-ounce servings. Comparable frozen vegetables not labeled with nutrition information have been found, in one case, to recommend a ½-cup serving and, in another case, to recommend a 3.3-ounce serving. Servings for canned tuna also appear to be unreasonably large since they are set at 6½ or 7 ounces.

Canned tuna labeling, which establishes a serving sometimes at 6½ and sometimes at 7 ounces, also points up the problem of nonuniform labeling within a product class, making comparison difficult. Another example of the lack of uniformity is in the labeling of vegetable juice. One brand of tomato juice currently states its serving size to be 8 ounces, while a different brand of vegetable juice sets its serving at 6 ounces.

Samples of representative labeling illustrating these problems are on display in the office of the Hearing Clerk.

Because of the industry's failure in many cases to establish reasonable and uniform serving sizes, the Commissioner is publishing a proposal to establish a procedure for prescribing appropriate servings and portions for use with nutrition labeling. The proposal also contains a procedure whereby interested persons may petition the Commissioner to establish an appropriate serving or portion.

The Commissioner notes that some of the present labeling confusion may be the result of an erroneous interpretation of the term "portion." Although portion size is intended to be used as a basis for nutrition labeling only for foods not eaten directly but eaten only as an ingredient of other foods, the term is being used improperly for such foods as canned peaches, canned green beans, canned peas, canned pears, canned tuna, and wieners. These foods are obviously eaten alone frequently, and a statement of the serving size rather than a portion size is therefore required. Although a portion is numerically the same as would be a serving of the food, since a portion expresses the amount of the ingredient present in a serving of the food of which it is an ingredient, the use of the term should be restricted as the regulation requires in order to avoid consumer confusion.

The Commissioner therefore proposes to amend § 1.17 to clarify this distinction.

The proposal also establishes serving sizes for several foods. Serving sizes for noncarbonated breakfast beverage products, hot and cold cereal, and formulated meal replacements are established at the same amounts as in the nutritional quality guidelines for those foods published elsewhere in this issue of the FEDERAL REGISTER. A serving size is established for fluid milk beverages at 8 ounces, the amount in a normal beverage glass, and a daily consumption amount at 1 quart, both of which have been standardized by the industry.

The Commissioner has not yet determined the appropriate serving sizes for the other foods discussed in this preamble, i.e., canned and frozen fruits and vegetables, and canned tuna. Trade associations may wish to consider petitions to establish reasonable serving sizes for such foods pursuant to the provisions of this proposal. If divergent serving sizes continue to be used in the marketplace and such petitions are not filed, the Commissioner will propose serving sizes for these foods on his own initiative.

Pertinent data and information in support of this proposal are on public display in the office of the Hearing Clerk.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201, 403, 701(a), 52 Stat. 1040–1042 as amended, 1047–1048 as amended, 1055 (21 U.S.C. 321, 343, 371(a))) and under authority delegated to him (21 CFR 2.120), the Commissioner proposes to amend Chapter I of Title 21 of the Code of Federal Regulations as follows:

1. In Part 1 by revising the introductory text of paragraph (b) and paragraph (b)(1) of § 1.17 to read as follows:

§ 1.17 Food; nutrition labeling.

* * * * *

(b) All nutrient quantities (including vitamins, minerals, calories, protein, carbohydrate, and fat) shall be declared in relation to the average or usual serving or, where food is customarily not consumed directly, in relation to the average or usual portion. The serving or portion size used shall be that established in Part 101 of this chapter or, if one is not so established in that part for the food, shall be determined in accordance with the provisions of this paragraph. Another column of figures may be used to declare the nutrient quantities in relation to the average or usual amount consumed on a daily basis, in the same format required in paragraph (c) of this section for the serving (portion), where reliable data have established that the food is customarily consumed more than once during the day and the average or usual amount so consumed.

(1) The term "serving" means that reasonable quantity of food suited for or practicable of consumption as part of a meal by an adult male engaged in light physical activity, or by an infant or child under 4 years of age when the article purports or is represented to be for consumption by an infant or child under 4 years of age. The term "portion" means the amount of a food customarily used in a serving of a meal component of which it is an ingredient. A label statement regarding a serving (portion) shall be in terms of a convenient unit of measure that can be easily identified as an average or usual serving (portion) and can be readily understood by purchasers of such food, e.g., a serving (portion) may be expressed in slices, cookies, or wafers; or in terms of ounces, fluid ounces, teaspoonfuls, tablespoonfuls, or cupfuls.

* * * * *

2. In Subchapter B by adding a new Part 101 to consist initially of the following:

PART 101—SERVING AND PORTION SIZES AND DAILY CONSUMPTION AMOUNTS

Subpart A—General

Sec.
101.1 General principles.
101.2 Petitions.

Subpart B—Serving and Portion Sizes and Daily Consumption Amounts

101.20 Noncarbonated breakfast beverage products.
101.21 Formulated meal replacements.
101.22 Ready-to-eat breakfast cereal.
101.23 Hot breakfast cereal.
101.24 Fluid milk beverages.

AUTHORITY: Secs. 201, 403, 701(a), 52 Stat. 1040–1042, as amended, 1047–1048 as amended, 1055 (21 U.S.C. 321, 343, 371(a)).

Subpart A—General

§ 101.1 General principles.

General principles governing the establishment of a serving or portion size or an amount consumed on a daily basis for a food under Subpart B of this part are as follows:

(a) A serving size shall identify that reasonable quantity of food suited for or practicable of consumption as part of a meal by an adult male engaged in light physical activity, except as provided in paragraph (c) of this section.

(b) A portion size shall be established only for a food customarily used only as an ingredient in other foods. A portion size shall identify that amount of the food customarily used in a serving, as defined in this section, of the meal component of which it is an ingredient.

(c) A serving size or portion size for an infant or child under 4 years of age shall be based on that reasonable quantity of food suited for or practicable of consumption as part of a meal by an infant or child under 4 years of age. Such a serving size or portion size shall be used only when the article of food purports or is represented to be for consumption by an infant or child under 4 years of age.

(d) Any serving size or portion size established shall be in terms of a convenient unit of the food or a convenient unit of measure that can be easily identified as an average or usual serving or portion and can be readily understood by purchasers of such food, e.g., a serving (portion) may be established in slices, cookies, or wafers; or in terms of ounces, fluid ounces, teaspoonfuls, tablespoonfuls, or cupfuls.

(e) An amount of a food consumed on a daily basis shall be based upon reliable data which establish that the food is customarily consumed more than once during the day and the average or usual amount so consumed.

§ 101.2 Petitions.

The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to establish or amend, under Subpart B of this part, a regulation prescribing a serving size or portion size for a food. Any such petition shall include an adequate factual basis to support the petition, shall be in the form set forth in § 2.65 of this chapter, and will be published for comment if it contains reasonable grounds for the proposed regulation.

Subpart B—Serving and Portion Sizes and Daily Consumption Amounts

§ 101.20 Noncarbonated breakfast beverage products.

The serving size of a noncarbonated breakfast beverage product shall be 6 fluid ounces, except that the serving size for infants and children under 4 years of age shall be 4 fluid ounces.

§ 101.21 Formulated meal replacements.

The serving size of a formulated meal replacement shall be the amount that, when finally constituted for consumption, is intended to replace a single meal.

§ 101.22 Ready-to-eat breakfast cereal.

The serving size of ready-to-eat breakfast cereal shall be 1 ounce, except that a serving for a single service container shall be the amount in the container. A serving of milk with ready-to-eat breakfast cereal shall be 4 fluid ounces.

§ 101.23 Hot breakfast cereal.

The serving size of hot breakfast cereal shall be 1 ounce, dry, uncooked form (15 percent moisture).

§ 101.24 Fluid milk beverages.

The serving size of a fluid milk beverage shall be 8 fluid ounces. The amount of a fluid milk beverage consumed on a daily basis shall be 1 quart.

Interested persons may, on or before August 13, 1974, file with the Hearing Clerk, Food and Drug Administration, Rm. 6–86, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding the petition and the Commissioner's proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: June 7, 1974.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.74-13473 Filed 6-13-74;8:45 am]

[21 CFR Parts 1, 102]

FOOD LABELING; LABEL DECLARATION OF INGREDIENTS; MISLEADING VIGNETTES; COMMON OR USUAL NAME FOR FOOD

Proposed Requirements

The Commissioner of Food and Drugs has recently amended several food labeling regulations and has published proposals for additional amendments. Some of the new regulations contain provisions relating to specific designated foods that should properly be made applicable to all food. In order to clarify food labeling requirements and minimize the potential for conflicting food labeling regulations, the Commissioner is proposing revision of and addition to existing food labeling regulations as specified in this notice.

LABEL DECLARATION OF INGREDIENTS

In some cases it has been established that differences in various forms of an ingredient (e.g., liquid, concentrated, dried, or frozen) do not result in any change in the allergenic potential of, or any detectable difference in, the finished food. On this basis, recent amendments to standards of identity have provided for label declaration of various forms of certain ingredients by use of a single

class name. For example, certain standards of identity for cheese products were amended in the FEDERAL REGISTER of April 23, 1973 (38 FR 9996), to allow milk, concentrated milk, and dried milk to be designated on the label as "milk".

The Commissioner is therefore proposing revision of § 1.10 (21 CFR 1.10) to provide for the same manner of label declaration of such ingredients for nonstandardized as well as standardized food. This is consistent with Food and Drug Administration policy that all food, whether standardized or nonstandardized, should be subject to the same labeling requirements.

The listing of groups of ingredients in the regulation that may be declared by single class names is not intended to be a complete listing of all such groups. Comments on this proposal should be limited to the proposed designations since the list will not be expanded at the final order stage. Any additions to the list will be accomplished by separate proposals to amend the regulation and therefore are more appropriately the subject of petitions rather than comments on this proposal.

The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may propose amendments to the provisions of § 1.10 specifying the manner or alternatives by which an ingredient shall be declared (i.e., specific or class name). Any such petition shall include an adequate factual basis to support the petition, shall be in the form set forth in § 2.65 of the regulations (21 CFR 2.65) and will be published for comment if it contains reasonable grounds for the proposed amendment.

PERCENTAGE OF CHARACTERIZING INGREDIENTS

The present § 1.10(d), as amended in the FEDERAL REGISTER of March 14, 1973 (38 FR 6966), provides that: "A label may be required to bear the percentage(s) of a characterizing ingredient(s) or information concerning the presence or absence of an ingredient(s) or the need to add an ingredient(s) as part of the common or usual name of the food pursuant to Subpart B of Part 102 of this chapter."

The Commissioner proposes that, since this provision is applicable to the requirements for a statement of identity, it should be transferred to § 1.8 of the regulations.

LABEL DECLARATION OF STANDARDIZED FOOD INGREDIENTS

The existing requirements concerning label declaration of ingredients in § 1.10 (a) provide that: "If an ingredient (which itself contains two or more ingredients) conforms to a definition and standard of identity prescribed by regulations under section 401 of the act, such ingredient may be designated on the label of such food by the name specified in the definition and standard, supplemented, in case such regulations require the naming of optional ingredients present in such ingredient, by a statement showing the optional ingredients which are present in such ingredient." Since the Food and Drug Administration is now moving toward full label declaration of all optional ingredients in standardized foods, this regulation needs revision.

The Commissioner therefore proposes to amend § 1.10 to provide that this label information may be presented on the label by either of the following alternatives: (1) By declaring the optional ingredients of the standardized food parenthetically after the name of the standardized food, or (2) by declaring the ingredients of the standardized food in their own order of predominance in the finished food, in which case the mandatory ingredients of the standardized food must also be declared. For example, macaroni used as an ingredient in another food may be declared in its order of predominance as "macaroni (seasoned with onions and celery, disodium phosphate added for quick cooking)", or all ingredients used to make the macaroni may be declared in their order of predominance in the finished food. Where future modifications of standards are promulgated to require label declaration of additional optional ingredients, or mandatory ingredients, the proposed revision of § 1.10 would, without further modification, also require label declaration of these ingredients regardless of which alternative manner of label declaration of ingredient is used.

In addition to the provisions concerning the label declaration of ingredients in standardized food, it is proposed that ingredients of foods for which there are USDA meat and poultry standards or for which common or usual names are established in 21 CFR Part 102 may be declared in the same manner, except that the provision with respect to nondeclaration of mandatory ingredients in the case of standardized foods is not applicable for USDA standards and common or usual names established under Part 102.

BREAKFAST SIRUPS

A proposal was published in the FEDERAL REGISTER of October 2, 1970 (35 FR 15403), to establish a standard of identity for table sirups. A final regulation, which will govern the labeling of these foods, is published elsewhere in this issue of the FEDERAL REGISTER. Consequently, the proposed revision of § 1.10 omits the requirement concerning such sirups presently found in paragraph (d).

FATS AND OILS

In the FEDERAL REGISTER of June 15, 1971 (35 FR 11521), the Commissioner published a proposed statement of policy on ingredient statements regarding fats and oils. Based in part on comments received in response to that proposal, provisions prescribing the manner of label declaration for fat and oil ingredients in foods have been included in the proposed revision of § 1.10. The Commissioner is publishing elsewhere in this issue of the FEDERAL REGISTER a notice terminating the rule making proceedings begun by the June 15, 1971 proposal.

The new proposal has the effect of requiring labeling that informs the consumer of the identity and, in many cases, the order of predominance of fat and oil ingredients in foods. Consumers' responses to the 1971 proposal showed a unanimity of opinion in favor of the mandatory declaration of the source of fat on all foods for health and medical reasons, in addition to their basic right to know such ingredients.

This proposal would require the specific name of fats and/or oils to appear in the ingredient listing of shortenings, blends of fats and oils, and in foods in which fats and oils are used, except that a strict order of predominance is not required for each fat or oil in foods that are not solely fats and/or oils and where fats and/or oils are not the predominant ingredient in the food.

The proposed requirements regarding fats and oils are not an unreasonable burden on manufacturers. The exceptions for specifying the order of predominance will permit manufacturers reasonably and freely to shift the proportion of fat sources in the fabrication of multi-ingredient foods, based on wholesale market price fluctuations, without having to make costly changes in labels. Consumers who wish to avoid a particular fat in a food would rarely, if ever, be benefited by being informed that there is a greater quantity present of one kind of fat than another.

Since this proposal requires labeling that informs the consumer of the identity of the fat and oil ingredients in food, the Commissioner proposes to rescind, at the time the final order is published, the opinions expressed in trade correspondences, TC–62, TC–94 and TC–209 (issued February 15 and 21, and March 21, 1940 respectively). TC–62 has allowed the hardened fat or oil to be declared in the ingredients statement as such without naming the individual oil beyond its vegetable, animal or marine origin. TC–94 has allowed various shortenings in fabricated foods to be declared in the ingredients statement solely as "shortening" without naming each specific fat or oil when the particular shortening cannot always be predicted in advance. TC–209 has allowed vegetable oil used for frying potato chips, to be declared in the ingredients statement as "cooked or fried in vegetable oil".

MISLEADING VIGNETTES

Section 1.15(a) (21 CFR 1.15(a)) states that "Among representations in the labeling of a food which render such food misbranded is a false or misleading representation with respect to another food or a drug, device or cosmetic." In the FEDERAL REGISTER of August 2, 1973 (38 FR 30740), the Commissioner promulgated a regulation establishing common or usual names for foods packaged for use in the preparation of "main dishes" or "dinners" (21 CFR 102.12). The regulation provides that any vignette which shows any food or charac-

terizing ingredient(s) or component(s) not included in the package shall be accompanied either (1) by an appropriate informative statement that additional characterizing ingredient(s) or component(s) must be added and which names the additional characterizing ingredient(s) or component(s), or (2) by a separate statement specifying the food or characterizing ingredient(s) or component(s) shown in the vignette but not included in the package.

The Commissioner proposes to extend this requirement to cover all foods since it is recognized that to require this labeling only for the "dishes" or "dinners" specified in § 102.12 would be confusing and misleading.

The Commissioner also proposes to revoke paragraph (c) of § 102.12 if the order ruling on this proposal incorporates like requirements for all foods.

OLIVE OIL MIXTURES

The proposed revision of § 1.10 would omit the example given in present paragraph (d) regarding mixtures of cottonseed oil and olive oil containing 80 percent or more of the cottonseed oil. Instead, the Commissioner proposes to establish a common or usual name under Part 102 (21 CFR Part 102) for mixtures of edible fat or oil and olive oil, which would require the declaration of the percent of olive oil in any such mixture. Since olive oil in such mixtures is a characterizing ingredient which has a material bearing on price and consumer acceptance of such mixtures, as set forth in 21 CFR 102.1(b), the Commissioner believes it appropriate to establish a common or usual name for such mixtures which includes the percent of olive oil.

Therefore, in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201(n), 403, 701(a), 52 Stat. 1041, 1047 as amended, 1055 (21 U.S.C. 321(n), 343, 371(a))) and under authority delegated to him (21 CFR 2.120), the Commissioner of Food and Drugs proposes to amend Chapter I of Title 21 of the Code of Federal Regulations as follows:

1. Part 1 is amended:

a. By adding a new paragraph (f) to § 1.8 to read as follows:

§ 1.8 Food in package form, labeling; identity.

* * * * *

(f) A label may be required to bear the percentage(s) of a characterizing ingredient(s) or information concerning the presence or absence of an ingredient(s) or the need to add an ingredient(s) as part of the common or usual name of the food pursuant to Subpart B of Part 102 of this chapter.

b. By revising § 1.10 to read as follows:

§ 1.10 Food; labeling; designation of ingredients.

(a) Ingredients required by section 403(i)(2) of the act to be declared on the label of a food, except those exempted by § 1.10a, shall be listed by common or usual name in descending order of predominance by weight on either the principal display panel or the information panel in accordance with the provisions of § 1.8d.

(b) The name of an ingredient shall be a specific name and not a collective (generic) name, except that:

(1) Spices, flavorings, colorings and chemical preservatives shall be declared according to the provisions of § 1.12.

(2) An ingredient which itself contains two or more ingredients and which has an established common or usual name, conforms to a standard established pursuant to the Meat Inspection or Poultry Products Inspection Acts by the U.S. Department of Agriculture, or conforms to a definition and standard of identity established pursuant to section 401 of the Federal Food, Drug, and Cosmetic Act, shall be designated in the statement of ingredients on the label of such food by either of the following alternatives:

(i) By declaring the established common or usual name of the ingredient followed by a parenthetical listing of all ingredients contained therein in descending order of predominance except that, if the ingredient is a food subject to a definition and standard of identity established in Subchapter B of this chapter, only the ingredients required to be declared by the definition and standard of identity need be listed; or

(ii) By incorporating into the statement of ingredients in descending order of predominance in the finished food, the common or usual name of every component of the ingredient without listing the ingredient itself.

(3) Skim milk, concentrated skim milk, and nonfat dry milk may be declared as "skim milk".

(4) Milk, concentrated milk, and dried milk may be declared as "milk".

(5) Bacterial cultures may be declared by the word "cultured" followed by the name of the substrate, e.g., "made from cultured skim milk or cultured buttermilk".

(6) Sweetcream buttermilk, concentrated sweetcream buttermilk, and dried sweetcream buttermilk may be declared as "buttermilk".

(7) Cheese whey, concentrated cheese whey, and dried cheese whey may be declared as "whey".

(8) Cream, dried cream, and plastic cream (sometimes known as concentrated milk fat) may be declared as "cream".

(9) Butteroil and anhydrous butterfat may be declared as "butter".

(10) Dried whole eggs, frozen whole eggs, and liquid whole eggs may be declared as "eggs".

(11) Dried egg whites, frozen egg whites and liquid egg whites may be declared as "egg whites".

(12) Dried egg yolks, frozen egg yolks, and liquid egg yolks may be declared as "egg yolks".

(13) An animal feed may be declared by a collective name listed in § 1.16 if it is a livestock or poultry feed within the meaning of sec. 201(x) of the act and meets the requirements for the use of a collective name as prescribed in § 1.16 for certain feed ingredients.

(14) Sugar (sucrose) shall be declared as "sugar", and invert sugar may be declared as "sugar".

(15) Sweeteners derived from corn may be declared as "corn sweeteners".

(16) Each individual fat and/or oil ingredient shall be declared by its specific common or usual name (e.g., "beef fat", "cottonseed oil") in its order of predominance in the food except that blends of fats and/or oils may be designated in their order of predominance in the food as "_____ shortening" or "blend of _____ oils", the blank to be filled in with the word "vegetable", "animal", "marine", with or without the terms "fat" or "oils", or combination of these, whichever is applicable if, immediately following the term, the common or usual names of the individual vegetable, animal, or marine fat or oil is given in parentheses, e.g., "vegetable oil shortening (soybean and cottonseed oil)". For products which are blends of fats and/or oils and for foods in which fats and/or oils are the predominant ingredient, the listing of the common or usual names of such fats and/or oils in parentheses shall be in descending order of predominance. In all other foods in which a blend of fats and/or oils is used as an ingredient, the listing of the common or usual names in parentheses need not be in descending order of predominance if the manufacturer, because of the use of varying mixtures, is unable to adhere to a constant pattern of fats and/or oils in the product. If the fat or oil is partially or completely hydrogenated, the name shall include the term "hydrogenated".

(17) Vinegar (cider vinegar, apple vinegar), wine vinegar (grape vinegar), malt vinegar, sugar vinegar, glucose vinegar, and spirit vinegar (distilled vinegar, grain vinegar) may be declared as "vinegar".

(18) When the ingredients of a cereal flour product are declared, the principal ingredient shall be declared by the name(s) specified in §§ 15.1, 15.40, 15.80 and 15.100 of this chapter, i.e., the first ingredient designated in the ingredient list of flour, or bromated flour, or enriched flour, or self-rising flour is "flour", "white flour", "wheat flour", or "plain flour"; the first ingredient designated in the ingredient list of "durum flour" is "durum flour"; the first ingredient designated in the ingredient list of whole wheat flour, or bromated whole wheat flour is "whole wheat flour", "graham flour", of "entire wheat flour"; and the first ingredient designated in the ingredient list of whole durum wheat flour is "whole durum wheat flour".

c. By adding the following new section:

§ 1.10b Petitions requesting exemptions from or special requirements for label declaration of ingredients.

The Commissioner of Food and Drugs, either on his own initiative or on behalf

of any interested person who has submitted a petition, may publish a proposal to amend § 1.10 to specify the manner in which an ingredient(s) shall be declared, i.e., by specific or class name, or § 1.10a to exempt an ingredient(s) from the requirements for label declaration. Any such petition shall include an adequate factual basis to support the petition, shall be in the form set forth in § 2.65 of this chapter and will be published for comment if it contains reasonable grounds in support of the proposed amendment.

d. By adding a new paragraph (d) to § 1.15 as follows:

§ 1.15 Food; labeling; misbranding.

* * * * *

(d) A vignette in the labeling of a food that depicts any food(s), characterizing ingredient(s), or component(s) not included in the food package shall be accompanied either:

(1) By an appropriate informative statement declaring that an additional food(s), characterizing ingredient(s), or component(s) must be added by the user, and specifying the additional food(s), characterizing ingredient(s), or component(s) which must be added, e.g., "you must add ____ to complete this meal", the blank to be filled in with the name(s) of the additional food(s), characterizing ingredient(s), or component(s) depicted but not present in the package; or

(2) By a statement specifying the food(s), characterizing ingredient(s), or component(s) shown in the vignette but not included in the package, e.g., "package does not contain ____", the blank to be filled in with the name(s) of the food(s), characterizing ingredient(s), or component(s) depicted but not present in the package.

(3) The statements required by this paragraph shall appear in an easily legible boldface print or type and in a height not less than one-sixteenth inch on packages having a principal display panel with an area of 5 square inches or less and not less than one-eighth inch if the area of the principal display panel is greater than 5 square inches.

2. Part 102 is amended:

§ 102.12 [Amended]

a. By revoking and reserving paragraph (c) of § 102.12.

b. By adding the following new section:

§ 102.19 Mixtures of edible fat or oil and olive oil.

The common or usual name of a mixture of edible fats and oils containing less than 100 percent and more than 0 percent olive oil shall be as follows:

(a) A descriptive name for the product meeting the requirements of § 102.1(a), e.g., "cottonseed oil and olive oil" or another descriptive phrase, and which lists all the fats and oils contained in the product in descending order of predominance, and

(b) When the label bears any representation, other than in the ingredient listing, of the presence of olive oil in the mixture, the descriptive name shall be followed by a statement of the percent of olive oil contained in the product in the manner set forth in § 102.1(b)(2).

Interested persons may, on or before August 13, 1974, file with the Hearing Clerk, Food and Drug Administration, Rm. 6–86, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: June 7, 1974.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.74–13467 Filed 6–13–74;8:45 am]

[21 CFR Part 3]

INGREDIENT STATEMENTS REGARDING FATS AND OILS IN FOOD FOR HUMAN CONSUMPTION

Withdrawal of Proposal and Termination of Rule Making Proceeding

In the FEDERAL REGISTER of June 15, 1971 (36 FR 11521), the Commissioner of Food and Drugs proposed to establish a statement of policy on ingredient statements regarding fats and oils.

Published elsewhere in this issue of the FEDERAL REGISTER is a proposed regulation regarding label declaration of ingredients in foods (including fats and oils). This proposal includes essentially all of the provisions of the statement of policy regarding fats and oils proposed on June 15, 1971.

Accordingly, the Commissioner hereby withdraws the proposal published on June 15, 1971 and terminates the rule making proceeding begun by that proposal.

This action is taken pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 403(i), 701(a), 52 Stat. 1048, 1055 (21 U.S.C. 343(i), 371 (a))) and under authority delegated to the Commissioner (21 CFR 2.120).

Dated: June 7, 1974.

Commissioner of Food and Drugs.
A. M. SCHMIDT,

[FR Doc.74–13479 Filed 6–13–74;8:45 am]

[21 CFR Part 15]

CEREAL FLOURS AND RELATED PRODUCTS

Proposed Improvement of Nutrient Levels of Enriched Farina

A notice of proposed rule making was published in the FEDERAL REGISTER of December 3, 1971 (36 FR 23074), in which the Commissioner of Food and Drugs, on his own initiative, proposed that the identity standards for enriched flour (21 CFR 15.10), enriched self-rising flour (21 CFR 15.60), enriched farina (21 CFR 15.140), and enriched bread, rolls, or buns (21 CFR 17.2) be amended to improve the nutrient levels, with particular reference to increasing the amount of iron. A final order ruling on that portion of the proposal which pertains to §§ 15.10, 15.60, and 17.2 appeared in the FEDERAL REGISTER of October 15, 1973 (38 FR 28558). As discussed below, the Commissioner concludes that a revised proposal should be issued concerning nutrient levels in enriched farina.

In comments filed in response to the proposal published in the FEDERAL REGISTER on December 3, 1971 (36 FR 23074), the Committee on Nutrition of the American Academy of Pediatrics, one company, and several professionals expressed the view that farina is consumed almost entirely as a breakfast cereal and that its use is not comparable to that of flour and bread. The Commissioner finds the suggestion that enriched farina should be considered a breakfast cereal reasonable, and has developed a new proposal for enriched farina so that fortification of this product will be consistent with similar breakfast cereals.

The Committee on Food Standards and Fortification Policy of the National Academy of Sciences/National Research Council (the NAS/NRC Committee) has submitted a recommendation on fortified breakfast cereals to the Commissioner. A copy of this report is on public display in the office of the Hearing Clerk, Food and Drug Administration, Rm. 6–86, 5600 Fishers Lane, Rockville, MD 20852. The NAS/NRC Committee recommendation has been used to develop the revised proposal on enriched farina. Separate proposed nutritional quality guidelines for fortified hot breakfast cereals and fortified ready-to-eat breakfast cereals are published elsewhere in this issue of the FEDERAL REGISTER.

Since a serving of breakfast cereal such as farina is commonly considered to be one ounce, the proposal states the amounts of vitamins and minerals that must be present on a per-ounce basis, rather than listing the nutrient content requirements in milligrams per pound as in enriched flour.

The NAS/NRC Committee recommended 25 percent of a mean Recommended Daily Dietary Allowance for thiamine, niacin, and iron and 15 percent for riboflavin and calcium in one ounce of breakfast cereals. The Commissioner concurs with the principle of this recommendation except as to iron. It appears that enriched farina is consumed by children up to 12 years of age and by people over the age of 65 years to a greater extent than by other segments of the population, and that members of both of these age groups may be particularly vulnerable to dietary inadequacies of iron. Accordingly, the Commissioner concludes that the proposal should provide for a level of iron moderately higher than the NAS/NRC Committee's recommendation, and thus the proposal specifies an iron level of 8.1 milligrams per ounce (45 percent of the U.S. RDA).

The present open-ended requirement for iron in enriched farina raises problems of possible over-enrichment. Previous observations have suggested that, with regard to foods where a range is permitted for enrichment ingredients,

some producers tend to aim for the minimum while others add the maximum amount and make unwarranted representations that their product is more nutritious. Accordingly, the Commissioner considers the establishment of single level requirement for iron, as well as for all other added nutrients, to be the most desirable approach.

Calcium is listed as an optional nutrient in the existing enriched farina standard, § 15.140 (21 CFR 15.140). The NAS/NRC Committee concluded that there is sufficient evidence of possible deficiencies of dietary calcium that this nutrient should be listed as a mandatory ingredient, and the Commissioner knows of no reason why enriched farina will not serve as efficiently as a calcium carrier as do other cereals. The NAS/NRC Committee pointed out that there probably is an excess of phosphorus in the American diet. Cereal grains commonly contain appreciable amounts of phosphorus; therefore, phosphorus was not included in the list of nutrients. The proposal to make calcium mandatory is an attempt to establish a desirable calcium-to-phosphorus ratio in light of the naturally occurring phosphorus in farina and the possibility of phosphate being added as a "quick cooking" agent.

If the proposal is adopted, vitamin D will no longer be a permissible nutrient for enriched farina. The NAS/NRC Committee did not recommend vitamin D enrichment in a cereal product and the Commissioner agrees that cereals generally are not suitable vehicles for vitamin D, especially since the milk with which enriched farina and other cereals are often eaten is a common and useful carrier of vitamin D.

The proposal does not permit niacin equivalents derived from tryptophan to be included in the total niacin content. The discussion of this subject in the preamble to the order amending the standards for enriched flour and bread, published in the FEDERAL REGISTER of October 15, 1973 (38 FR 28558), applies also to enriched farina.

The Commissioner also proposes that the standard be amended to permit the use of any safe and suitable ingredients that are functionally effective for reducing the cooking time of enriched farina with appropriate label declaration when such substances are used. It is also proposed that any safe and suitable substances may be used to supply the prescribed quantity of vitamins and minerals required by the standard for enriched farina.

Pursuant to 21 CFR 3.88, standards of identity are being amended to require label declaration of optional ingredients. An order amending the standards to require mandatory label declaration of optional ingredients in wheat flour and related products including enriched farina was published in the FEDERAL REGISTER of November 28, 1973 (38 FR 32787). The requirement appears in the revision proposed below.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 401, 701, 52 Stat. 1046, 1055–1056, as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 341, 371)) and under authority delegated to the Commissioner (21 CFR 2.120), it is proposed that Part 15 be amended by revising § 15.140 to read as follows:

§ 15.140 Enriched farina; identity; label statement of optional ingredients.

(a) Enriched farina conforms to the definition and standard of identity prescribed for farina by § 15.130, except that:

(1) It contains in each ounce, calculated to a 15 percent moisture basis, 0.38 milligram of thiamine, 0.26 milligram of riboflavin, 5.0 milligrams of niacin, 8.1 milligrams of iron, and 150 milligrams of calcium.

(2) The prescribed quantity of the vitamins and minerals referred to in paragraph (1) of this section may be supplied by any safe and suitable substances. Niacin equivalents as derived from tryptophan shall not be used in determining total niacin content.

(b) It may contain not more than 8 percent by weight of wheat germ or partly defatted wheat germ.

(c) It may contain or be treated with safe and suitable substances for reducing the cooking time, provided that the moisture limit prescribed by paragraph (a) of § 15.130 is adhered to.

(d) In determining whether the ash content complies with the requirement of this section, ash resulting from iron, iron salts, and calcium salts and from any added substance provided for in paragraphs (c) and (d) of this section shall not be included in computing ash content.

(e) All ingredients from which the food is fabricated shall be safe and suitable.

(f) (1) When cooking aids are added, the name of the food shall be immediately preceded or followed by the statement "_____ added for quick cooking", the blank being filled in with the name of the ingredient used, or "enzyme-treated for quicker cooking" as appropriate.

(2) All optional ingredients used shall be declared on the label as required by the applicable sections of Part 1 of this chapter.

Interested persons may, on or before August 13, 1974, file with the Hearing Clerk, Food and Drug Administration, Rm. 6–86, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: June 7, 1974.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.74–13471 Filed 6–13–74;8:45 am]

[21 CFR Parts 15, 102]

COMMON OR USUAL NAME FOR PLANT PROTEIN PRODUCTS; WITHDRAWAL OF TEXTURED PROTEIN PRODUCTS PROPOSAL

Notice of Proposed Rule Making

In the FEDERAL REGISTER of December 5, 1970 (35 FR 18530), the Commissioner of Food and Drugs in response to a petition filed jointly by Archer Daniels Midland Co., Post Office Box 1470, Decatur, IL 62525, and General Mills, Inc., 9200 Wayzata Boulevard, Minneapolis, MN 55440, proposed that a definition and standard of identity be established for a class of foods to be known as "Textured Protein Products" prepared from vegetable protein and other ingredients. This standard of identity was to be added to Part 15—Cereal Flours and Related Products under a new Subpart D—Textured Protein Products.

Thirty-six individuals and organizations commented on the proposed standard of identity for textured protein products. Thirty letters came from manufacturers and distributors of foods. Two were received from individuals. Four government agencies (Federal, State, local) responded to the proposed standard. The Commissioner has evaluated all of the comments.

Ten of the respondents supported the proposal in its entirety. The reasons given for support of the proposal were: (a) The standard would benefit both food processors and consumers; (b) it would create assurances that desired nutritional values are maintained; (c) it would assist in standardizing labeling of foods containing textured protein; and (d) it would enable the development of new protein-containing foods at a time of worldwide concern about an adequate protein supply.

Several comments suggested that no standard of identity for textured protein products be adopted at this time. Reasons given in support of this view included: (a) The manufacture and use of cereal and vegetable protein products is rapidly expanding, and establishing a rigid standard of identity would restrict the development of new technology; (b) guidelines should be published with respect to the nutritional quality of the products instead of establishing a standard of identity; and (c) the proposal is so loosely drawn that it would give manufacturers free rein on product labeling.

The Commissioner recognizes that in the time since the proposal was published there has been a tremendous increase in the use of vegetable flours and of protein products derived from them in new food substances, and that the technology of these foods is still in a very active stage of development. In view of this and the fact that consumer recognition and understanding of these foods is only just beginning, the Commissioner now believes that, in lieu of the proposed standard of identity, common or usual names should be established for plant protein

products used as extenders and replacements for major protein foods.

Therefore, the Commissioner is terminating action on the proposed definition and standard of identity published December 5, 1970 (35 FR 18530), and as set forth below, is publishing a proposal to establish common or usual names for the class of protein foods prepared predominantly from cereal and vegetable products and used as extenders or replacements for meat, seafood, poultry, eggs, or cheese.

The Commissioner concludes that there are three subclasses of plant protein products used as extenders or replacements for major animal protein sources that should be distinguished by common or usual names. Each of these subclasses is distinguished by the ratio of protein to other material present in the product, and because this ratio affects the product's taste and other physical characteristics, the Commissioner believes that consumers are misled if they are not informed of those differences. The proposed divisions between the subclasses take into account the manufacturing processes employed, and the common or usual names proposed are similar to the names presently employed in the industry to identify the three subclasses. The three types of plant protein products used as extenders or replacements are as follows:

a. A product that is principally the unmodified or only slightly modified cereal grain or vegetable product. Such slightly modified products have protein contents less than 65 percent by weight on a moisture-free basis. They include cereal or vegetable flours and granular products which have been defatted, dehydrated, and physically changed, e.g., ground or extruded, but which retain most of the chemical properties of the source plant. The common or usual name of plant protein products used as extenders or replacements that contain less than 65 percent protein on a moisture-free basis is proposed to be the name(s) of the source(s) and a term which accurately describes the physical form of such product, e.g., "soy flour" or "soy granules".

The Commissioner concludes that the source of the protein must be identified because of the chemical differences between vegetable sources.

b. A product in which some of the nonprotein components of the basic plant source have been eliminated. Such a product has a protein content between 65 and 90 percent by weight and is frequently referred to in the trade as a "concentrate." This term is appropriate since the processing (extraction, washing, etc.) has concentrated the protein component by eliminating part of the fiber, carbohydrate, and mineral content of the source. The common or usual name of plant protein products used as extenders or replacements that contain at least 65 percent but less than 90 percent on a moisture-free basis is proposed to be "____ protein concentrate", the blank to be filled in with the name(s) of the source(s). The general terms "cereal", "vegetable", or "plant" may be used if the protein concentrate is derived from more than two sources.

c. A product having a protein content of at least 90 percent. These plant protein products, which are frequently almost pure protein, are prepared by dissolving protein from source material and recovering the protein in essentially pure form from solution, hence the industry term "isolate." Identification of source plants in the common or usual name is optional since isolates have fewer of the chemical properties of the source. The common or usual name of a plant protein product used as an extender or replacement that contains at least 90 percent protein on a moisture-free basis is proposed to be "____ protein isolate", the blank to be filled in with the specific name of the source or with the term "vegetable", "cereal", or "plant".

The Commissioner recognizes that many plant protein product extenders and replacements consist of a mixture of plant protein product components. The common or usual names for such mixtures would ordinarily consist of the common or usual name of each component. To avoid names which are so long and complex as to be cumbersome and confusing, in the proposed rules the name of a mixture may include the term "plant protein product" when the mixture consists of three or more plant protein product components, as follows:

a. When the mixture consists of protein concentrate(s) and protein isolate(s), the term "plant protein product" may be used alone or with terms which accurately describe the physical form of the mixture, e.g., "granules" or "bits".

b. When the mixture consists of a product with a protein content less than 65 percent as well as protein concentrate(s) and protein isolate(s), the designation may be "plant protein product and ____" or "____ and plant protein product", whichever reflects the descending order of predominance. The blank is to be filled in with the common or usual name of the other component(s) except that the term "vegetable", "cereal", or "plant" may be used in place of the name of the source plant in that name when there is more than one source involved, e.g., "vegetable flours and plant protein product". The designation may be used alone or with terms which accurately describe the physical form of the mixture.

The Commissioner recognizes that most of the plant protein products used to extend or replace meat, seafood, poultry, eggs, or cheese are processed to produce acceptable physical characteristics and that terms such as "texturized" and "textured" have been used as part of the names for these foods. The proposal permits the use of such qualifying words with any of these products as long as they accurately describe the product and do not mislead the consumer.

In a change from the 1970 proposal, this proposal is not limited to certain vegetable protein sources. Comments to the 1970 proposal were concerned that protein sources such as corn, mustard seed, barley, rice, and rapeseed were not permitted. The vegetable protein sources originally proposed were those either in use or for which sufficient developmental work had demonstrated that they were suitable for the manufacture of plant protein products.

The Commissioner recognizes that due to the rapid changes in food technology more protein sources will become available and that, therefore, it would be in the best interest of the consumer, from both nutritional and functional standpoints, to allow the use of other plant protein sources as long as it can be demonstrated that the materials are safe and suitable protein sources. In addition, animal proteins such as milk protein, fish protein concentrate, and egg protein can be used in the fabrication of a protein product and should be permitted.

The Commissioner concludes that a plant protein product that is represented or used as an extender or replacement for meat, seafood, poultry, eggs, or cheese is a substitute for and resembles that food when used. It is, therefore, an imitation of that food under 21 CFR 1.8(e) if it is nutritionally inferior to the food it simulates. Consequently, the proposal identifies the nutritional qualities of plant protein product extenders and replacements that will avoid the necessity of their being labeled as imitations. These nutritional qualities include the quantity of protein present in the finished food, the quality of that protein, and the amount of vitamins and minerals present.

The amount of protein proposed to be required in plant protein products, when ready for consumption, has been based upon the protein content of primary animal protein sources. As proposed below, the protein content of a plant protein product offered as a replacement or extender for meat, seafood, poultry, eggs, or cheese must be at least 18 percent when hydrated according to the manufacturer's directions. The 18-percent level is similar to the protein levels in meat and seafood.

The Commissioner has considered those comments to the 1970 proposal which suggested that it might be necessary to require a different protein quantity for each type of food simulated (meat, fish, cheese, etc.). These comments are consistent with the statement of the Council on Foods and Nutrition of the American Medical Association and the Food and Nutrition Board of the National Academy of Sciences/National Research Council in the publication "General Policies in Regard to Improvement of Nutritive Quality of Foods," September 1968, National Academy of Sciences, Washington, DC, that the "protein content and PER should be based on the protein of the food simulated."

The Commissioner concludes, however, that it would be in the best interest of the consumer to establish a uniform minimum amount of protein for all plant protein products rather than to establish a different minimum quantity for each type of food simulated. The quan-

tity of protein in traditional foods varies not only from one type of food to another, but also within each food type. Requiring a plant protein product to have a different level of protein for each different food it extends or replaces is not practical nor is it necessary to protect the consumer against nutritionally inferior imitations.

To maintain nutritional equivalence with the food simulated, the protein quality of the plant protein product must also be considered. When a cereal or vegetable source of protein is combined in a large proportion with meat, seafood, poultry, eggs, or cheese, or when it is used by itself to simulate an animal protein source, the protein quality of the plant protein product must be equal to that of the animal protein source.

When the proportion of plant protein added is smaller, however, the protein quality of the final product will be dependent primarily on the quality of the animal protein, and the Commissioner concludes it is appropriate to establish a lower minimum protein quality for these products. Since definitive data are lacking on the ratio of plant protein to animal protein necessary to provide a mixed protein of a quality similar to the animal protein, the Commissioner proposes, as a conservative approach, that lower quality protein will be permitted only if the hydrated plant protein product is 30 percent or less of the finished food. If the hydrated plant protein product is 30 percent or less of the finished food, the product is considered an extender, and a minimum protein efficiency ration (PER) of 80 percent of casein is proposed. If the hydrated plant protein product constitutes more than 30 percent of the finished food, the product is a replacement for the animal protein, and the proposal establishes a minimum PER of 108 percent of casein. These PER requirements are compatible with proposed USDA requirements for meat products that contain nonmeat ingredients (38 FR 11093). Different PER's for each food simulated are impractical because protein quality varies from one type of food to another and also within each food type.

Some comments to the 1970 proposal objected to the use of casein as a reference standard for determining protein quality. Casein has an acceptable essential amino acid pattern and is recognized as a good quality protein. The use of casein as a reference standard in determining the PER of protein is in accordance with the method described in §§ 39.166–39.170, "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th edition, 1970.[1] A uniform supply of casein can be obtained, whereas a uniform supply of other purified proteins such as lactalbumen and whole egg is not readily available. The Commissioner recognizes the limitations of the casein PER test. At this time, however, it is the only official method available for regulatory purposes.

The levels of vitamins and minerals must also be equivalent to the food simulated, but, again, because of the impracticalities of adjusting the required levels to each type of food, uniform requirements (except for cheese) are proposed. The vitamin and mineral content of cheeses and of certain raw forms of meats and seafood have been used as guides in setting the proposed requirements. The average values of the nutrients per 100 grams of the edible portion of these animal protein sources have been converted to the amount of nutrient per gram of protein.

Relating nutritional requirements to protein is a change from the 1970 proposal which related them to caloric levels. The Commissioner recognizes that caloric intake is one of the controlling factors of food consumption and has, for example, expressed minimum nutrient levels on a caloric basis in the nutritional quality guideline for frozen "heat and serve" dinners (21 CFR 100.5).

The Commissioner concludes, however, that setting vitamin and mineral levels based on the amount of protein can also provide the necessary control and is more appropriate here. Moreover, since the proposal establishes a minimum level of protein for extenders or replacements as used, relating levels of other nutrients to the protein content would assure a minimum nutrient level in the finished food.

If a plant protein product simulates cheese, the proposal establishes levels for vitamin A, calcium, and phosphorous consistent with those in cheese. Values based on average values for various kinds of cheese have been used to establish the guideline levels for these nutrients in products extending or replacing cheese.

Since plant protein products are often used as ingredients in finished foods rather than as finished foods themselves, it is approriate to establish names for such finished foods too. When a finished food contains a plant protein product extender or replacement but as a whole resembles the meat, seafood, poultry, eggs, or cheese with which the plant protein product is mixed, the proposal requires both the traditional component and the plant protein product to be named in the same type size. An example of this type of food is a mixture of cheese and plant protein product which resembles cheese when sold. If a plant protein product is used to extend or replace meat, seafood, poultry, eggs, or cheese as one of the characterizing components in a multicomponent food, the proposal provides that the name of the finished food is to be followed immediately by or appear directly above the name of the component containing the plant protein product in type size at least half the size of the name of the finished food. An example of this type of food is pizza which contains "cheese" made in whole or in part of plant protein product.

Finally, the proposal provides for a label declaration of sodium under certain circumstances. Some of the flavors, colors, binders, and other ingredients used in plant protein products may be added in the form of sodium salts, so that the sodium content of a finished food containing a plant protein product may be significantly greater than that of the food made with the traditional protein source which has been extended or replaced. This increase is a material fact required to be disclosed, since significant numbers of consumers are interested in controlling their sodium intake. A declaration of increased sodium is therefore required when there is a nutritionally significant increase.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201(n), 401, 403, 701, 52 Stat. 1041, 1047–1048 as amended, 1055–1056 as amended (21 U.S.C. 321(n), 341, 343, 371)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120):

1. Notice is given that further action on the proposal to establish a definition and standard of identity for textured protein products published in the FEDERAL REGISTER of December 5, 1970 (35 FR 18530), is withdrawn without prejudice as to the filing of a new proposal at a later date.

2. It is proposed that a new § 102.22 be added to Subpart B of Part 102 to read as follows:

§ 102.22 Plant protein products.

(a) Among plant protein products, the common or usual names of extenders and replacements for meat, seafood, poultry, eggs, or cheese, which are produced from safe and suitable edible plant protein sources, including, but not limited to, soybeans, peanuts, wheat, and corn, are as follows:

(1) When the product contains less than 65 percent protein by weight on a moisture-free basis, the name shall consist of the name(s) of the source(s) of the protein and a term which accurately describes the physical form of the product, e.g., "soy flour" or "soy granules." The word "protein" shall not be included in this name.

(2) When the product contains 65 percent or more but less than 90 percent protein by weight on a moisture-free basis, the name shall be "_____ protein concentrate", the blank to be filled in with the name(s) of the source(s) of the protein, e.g., "soy" or "peanut". The term "vegetable", "cereal", or "plant" may be used if the plant protein is derived from more than two sources. The name may be accompanied by a term that describes the physical form of the product, e.g., "bits" or "granules".

(3) When the product contains 90 percent or more protein by weight on a moisture-free basis, the name of the product shall be "_____ protein isolate", the blank to be filled in with the name(s) of the source(s) of the protein, e.g., "soy", or with the term "vegetable", "cereal", or "plant". The name may be accompanied by a term that describes the physical form of the product, e.g., "bits" or "granules".

(4) When the product is a mixture of the products described in paragraph (a) (2) and (3) of this section, the name of the mixture shall consist of the common or usual names of the components in de-

[1] See footnote on next page.

scending order of predominance. Alternatively, a mixture of three or more such products may be designated "plant ("vegetable" or "cereal") protein product". In either case, the name may be accompanied by a term that describes the physical form of the product, e.g., "bits" or "granules".

(5) When the product is a mixture of the products described in paragraph (a) (1), (2), and (3) of this section, the name shall consist of the common or usual names of the components in descending order of predominance. Alternatively, a mixture of three or more such products may be designated "plant protein product and _____" or "_____ and plant protein product", whichever reflects the descending order of predominance. The blank in such designation shall be filled in with the common or usual name of the component(s), described in paragraph (a) (1) of this section, except that the term "vegetable", "cereal", or "plant" may be used in place of the name of the source plant when there is more than one source involved.

The name may be accompanied by a term that describes the physical form of the product, e.g., "bits" or "granules".

(b) The common or usual name of a product described in paragraph (a) of this section shall include an appropriate flavor declaration if the product is flavored to resemble meat, seafood, poultry, eggs, or cheese. Such flavor declaration shall be in compliance with § 1.12 of this chapter, e.g., "soy flour, ham flavored" or "artificially ham-flavored soy protein concentrate".

(c) The common or usual name of a product described in paragraph (a) of this section may include the term "textured" or "texturized" when such term is appropriate.

(d) When a product described in paragraph (a) of this section contains added animal protein, such as milk protein, fish protein concentrate, or egg protein, the common or usual name shall include that source in descending order of predominance, e.g., "plant and fish protein concentrate" or "animal and plant protein concentrate".

(e) A plant protein product which acts as an extender or replacement for meat, seafood, poultry, eggs, or cheese, but which is nutritionally inferior to that animal protein source, shall be labeled as an imitation of the animal protein source for which it substitutes and which it resembles, pursuant to § 1.8(e) of this chapter. For purposes of § 1.8(e) of this chapter, a plant protein product shall be considered nutritionally equivalent to the meat, seafood, poultry, eggs, or cheese it extends or replaces if it meets all of the following conditions:

(1) When the plant protein product is hydrated according to the manufacturer's directions, its protein is at least 18 percent by weight of the hydrated product.

(2) If the hydrated plant protein product is not more than 30 percent by weight of the mixture when mixed with meat, seafood, poultry, eggs, or cheese, the biological quality of the protein (including amino acids added thereto) is at least 80 percent that of casein.

(3) If the hydrated protein product is more than 30 percent by weight of the mixture when mixed with meat, seafood, poultry, eggs, or cheese, or if the hydrated protein product is used unmixed in a way that it substitutes for and resembles meat, seafood, poultry, eggs, or cheese, the biological quality of the protein (including amino acids added thereto) is at least 108 percent that of casein.

(4) The plant protein product contains the following levels of nutrients per gram of protein:

Nutrient	*Amount*
Vitamin A (IU)	15.00
Thiamine (milligrams)	.014
Riboflavin (milligrams)	.01
Niacin (milligrams)	.30
Pantothenic acid (milligrams)	.040
Vitamin B_6 (milligrams)	.02
Vitamin B_{12} (μg)	.09
Iron (milligrams)	.13
Calcium (milligrams)	10.0
Phosphorus (milligrams)	10.0
Folic acid (μg)	.40
Magnesium (milligrams)	1.14
Zinc (milligrams)	.23

(5) If a plant protein product extends or replaces cheese in a cheese-like food, the plant protein product contains, per gram of protein, 54 international units of vitamin A, 26 milligrams of phosphorus, and 26 milligrams of calcium, instead of the amounts of those nutrients specified in paragraph (b) (4) of this section.

(f) Compliance with the moisture and protein requirements of paragraph (a) of this section shall be determined by the methods described in sections 14.076 and 14.078, respectively, of "Official Methods of Analysis of the Association of Official Analytical Chemists", 11th edition, 1970,[1] and the biological quality of protein requirements of paragraph (e) of this section by the methods in sections 39.166–39.170 of that book.

(g) When the substitution of a plant protein product for meat, seafood, poultry, eggs, or cheese results in an increase in the sodium content of a food by 25 milligrams or more per 100 grams, sodium content shall be declared on the label in accordance with §§ 1.17 and 125.9 of this chapter.

(h) A food which is, or which contains any plant protein product subject to this section shall be labeled as follows.

(1) The name of a finished food that as a whole resembles meat, seafood, poultry, eggs or cheese, and that contains a plant protein product for which a common or usual name is established in this section, but contains no meat, seafood, poultry, eggs, or cheese, shall be the name established in paragraphs (a) through (d) of this section.

[1] Copies may be obtained from:
Association of Official Analytical Chemists,
P.O. Box 540,
Ben Franklin Station,
Washington, DC 20044.

(2) The name of a finished food that as a whole resembles meat, seafood, poultry, eggs or cheese, and that contains both (i) a plant protein product for which a common or usual name is established in this section and (ii) meat, seafood, poultry, eggs, or cheese, shall include the names of such ingredients in descending order of predominance and in the same type size.

(3) The name of a multi-component finished food that contains as part or all of a characterizing component a plant protein product for which a common or usual name is established in this section shall be immediately followed by or shall be directly above the word "containing" (or "contains") and the name of the component containing the plant protein product in type size not less than one-half the height of the type of the name of the finished food.

Interested persons may, on or before August 13, 1974, file with the Hearing Clerk, Food and Drug Administration, Room 6–86, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: June 7, 1974.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.74–13470 Filed 6–13–74;8:45 am]

[21 CFR Part 100]

BREAKFAST BEVERAGE PRODUCTS

Proposed Nutritional Quality Guidelines

In the FEDERAL REGISTER of March 14, 1973 (38 FR 6969), the Commissioner of Food and Drugs promulgated a procedure and general principles for the establishment by regulation of nutritional quality guidelines for foods.

The Commissioner had earlier contracted with the National Academy of Sciences for assistance in identifying and defining the important classes of foods for which such nutritional quality guidelines should be etstablished and in providing proposed nutrient compositions for them which would be in the best interest of the public health. The recommendations of the Committee on Food Standards and Fortification Policy of the National Academy of Sciences/National Research Council (the NAS/NRC Committee) for ascorbic acid fortified vegetable juices, fruit juices, fruit drinks, and imitation fruit-flavored drinks have been received by the Commissioner. A copy of this report is on public display in the office of the Hearing Clerk, Food and Drug Administration, Rm. 6–86, 5600 Fishers Lane, Rockville, MD 20852.

The recommendations reflect the fact that some conventional vegetable and fruit juices are major sources of vitamin C in the diet, and that other such products which are not naturally good sources of the vitamin, and many flavored bever-

ages, have been fortified with vitamin C at various levels. The recommendations are intended to assure the consumer that when vitamin C is added to such a product it will provide a nutritionally adequate level of the vitamin but will not be in excess of nutritional requirements. Products subject to this proposed guideline include 100-percent (full strength) juices; products with less than 100 percent of natural juice; or juices, mixtures of juices, nectars, and products in dry or liquid form flavored to resemble a fruit or vegetable drink, which are in any way represented or suggested for use as breakfast beverages.

The NAS/NRC Committee recommended a minimum supplement level of 50 mg per 6 fl. oz. serving (or equivalent) and a maximum supplement level of 65 mg per 6 fl. oz. serving (or equivalent). These values represent the mean Recommended Daily Allowance (RDA) and an average ascorbic acid content of citrus juices, respectively.

The Commissioner concludes that one level, consistent with the newly established U.S. RDA (60 mg), should be proposed. Since this level of fortification is essentially the same as that occurring naturally in the various citrus juices, which are among the richest common sources of the vitamin, and since there is no known nutritional significance to supplemental intakes beyond this level, there is no justification for establishing an upper limit beyond 60 mg per average serving (6 fl. oz.). Moderate excesses, in accordance with good manufacturing practice, necessary to assure the consumer of label accuracy would, of course, be acceptable. Since the level of fortification exceeds the 50 percent of the U.S. RDA allowed in § 1.17 (21 CFR 1.17) for general food fortification as contrasted to dietary supplements, this proposal represents an exception from that general rule for this product class. Such an exception is justified since this class of foods constitutes the major source of vitamin C in the daily diet of most people. The "USDA Household Food Consumption Survey 1965–1966", a copy of which is on file with the Hearing Clerk, indicates that only about 30–58 percent of the recommended allowance is obtained from all other food sources combined. These USDA values have a wide variability depending upon individual food consumption patterns, but there is general agreement that the citrus fruits and juices, along with tomato juice, commonly consumed with breakfast, supply the major proportion of the daily dietary vitamin C.

The products included in this proposed guideline include all noncarbonated beverages which are represented or suggested for use as breakfast juice beverages. The proposal does not include products packaged and promoted to the consumer solely as refreshment drinks.

A serving size is proposed under this guideline. The 6 fl. oz. adult serving size proposed is the recommendation of the NAS/NRC Committee and as described above represents the amount of citrus juices necessary (on the average) to supply the recommended level of vitamin C. Since the quantitative volume or equivalent for dry products is essential for the guideline specification, there is little reason why this same amount could not constitute an appropriate serving size and be accepted as standard. For those products intended specifically for infants or children under 4 years of age, a serving size of 4 fluid ounces is reasonable.

The NAS/NRC Committee report stated that only vitamin C has been considered. The proposed guideline therefore does not cover the possible addition of other essential nutrients, since the variability of both kind and quantity of nutrients in the variety of juice products that can be prepared renders it impractical and inappropriate to establish specific guideline values for all nutrients in the entire class of foods. They are subject, on an individual basis, to the requirements of the imitation food regulation (21 CFR 1.8(e)).

Elsewhere in this issue of the FEDERAL REGISTER the Commissioner is proposing general principles for the addition of nutrients to foods wherein the terms "fortified" and "enriched" are defined. That proposal specifies that no label claims regarding added nutrients will be permitted unless such addition(s) constitutes at least 10 percent of the U.S. RDA for the nutrient(s). For breakfast beverage products which meet the proposed guideline and are "fortified" or "enriched" according to the definitions contained in that proposal, use of such statements as "fortified with vitamin C" or "enriched with vitamin C" is proper when vitamin C is added at a level equal to or greater than 10 percent of the U.S. RDA in a serving of the product.

The Commissioner recognizes that some standards of identity for canned fruit juices and juice drinks contain vitamin C fortification requirements which do not conform to this guideline. These standards will be reviewed and amended as necessary to bring them into agreement with the guideline. When a breakfast beverage product which conforms to a standard of identity which designates the nutrient additions permitted for the food, such product may bear the statement provided for in § 100.1 (b) (21 CFR 100.1(b)). Elsewhere in this issue of the FEDERAL REGISTER the Commissioner is proposing to amend § 100.1 to this effect.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201(n), 403, 701(a), 52 Stat. 1041 as amended, 1047–1048 as amended, 1055 (21 U.S.C. 321(n), 343, 371(a))) and under authority delegated to the Commissioner (21 CFR 2.120), it is proposed that Part 100 be amended by adding a new § 100.6 to Subpart B to read as follows:

§ 100.6 Noncarbonated breakfast beverage products.

(a) In order to bear the statement provided in § 100.1(b), a beverage product described in paragraph (b) (1) of this section shall contain 10 milligrams of vitamin C per fluid ounce when prepared for consumption according to the directions for use.

(b) (1) The beverage products subject to this regulation include any liquid or dry noncarbonated beverage product which contains any amount of fruit or vegetable juice or, if it contains no fruit or vegetable juice, is subject to the requirements of § 102.10 of this chapter, which is represented or suggested by the label or in labeling or advertising, directly or indirectly, for use as a breakfast beverage product.

(2) This section is not applicable to a refreshment beverage which is not represented or suggested for use as a breakfast beverage.

(c) A serving shall be 6 fluid ounces or, when the proudct is intended specifically for infants or children under 4 years of age, 4 fluid ounces.

(d) When the statement provided in § 100.1(b) is used, the words "provides vitamin C in the amount appropriate" shall replace the words "provides nutrients in amounts appropriate".

(e) A beverage product which meets the guideline and to which vitamin C has been added at a level equal to or greater than 10 percent of the U.S. RDA in a serving of the product may bear on its label the following: "____ with vitamin C", where the blank is filled in with the term "enriched" or "fortified", in accordance with § 100.1(j); or "with added vitamin C"; or a similar statement.

Interested persons may, on or before August 13, 1974 file with the Hearing Clerk, Food and Drug Administration, Rm. 6–86, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: June 7, 1974.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.74-13476 Filed 6-13-74;8:45 am]

[21 CFR Part 100]

FORTIFIED HOT BREAKFAST CEREALS

Proposed Nutritional Quality Guideline

In the FEDERAL REGISTER of March 14, 1973 (38 FR 6969), the Commissioner of Food and Drugs promulgated a procedure and general principles for the establishment by regulation of nutritional quality guidelines for foods.

The Commissioner had earlier contracted with the National Academy of Sciences for assistance in identifying and defining the important classes of foods for which such nutritional quality guidelines should be established and in providing proposed nutrient compositions for them which would be in the best interest of the public health. The recommendations of the Committee on Food Standards and Fortification Policy of the Na-

tional Academy of Sciences/National Research Council (the NAS/NRC Committee) for fortified breakfast cereals have been received by the Commissioner. A copy of this report is on public display in the office of the Hearing Clerk, Food and Drug Administration, Rm. 6–86, 5600 Fishers Lane, Rockville, MD 20852.

The concepts of this report were used to develop a proposed nutritional quality guideline for fortified ready-to-eat breakfast cereals, published elsewhere in this issue of the FEDERAL REGISTER. Although the NAS/NRC Committee did not differentiate between ready-to-eat cereals and hot cereals, the Commissioner concludes that there are sufficient differences in their consumption patterns to justify separate guidelines.

This nutritional quality guideline for fortified hot breakfast cereals provides for specified levels for iron and calcium in addition to the three B vitamins with which cereal products commonly are enriched. Although this course of action deviates from the NAS/NRC Committee's recommendation, it is in full accord with its intent in specifying nutrients for breakfast cereals. There is definite evidence (Ten-State Nutrition Survey and the 1965 USDA Food Consumption Survey, copies of which are on public display in the office of the Hearing Clerk) of the likelihood of shortage of iron, and possibly calcium, in the diets of those who commonly consume hot breakfast cereals.

Since cereals often form the basis of a breakfast, the NAS/NRC Committee decided that, in breakfast cereals to which nutrients are added, the nutrients (per serving) should be expressed as a percentage of a standard. The Food and Drug Administration has established the U.S. Recommended Daily Allowance (U.S. RDA) values for purposes of labeling. With a few exceptions, the U.S. RDA value is the highest value listed for each nutrient in the NAS/NRC tables of Recommended Daily Dietary Allowances. The derivation and use of the U.S. RDA values are discussed in detail in the preambles to special dietary foods (21 CFR Part 125) published in the FEDERAL REGISTER of January 19, 1973 (38 FR 2143), and August 2, 1973 (38 FR 20708); and nutrition labeling (21 CFR Part 1) and dietary supplements of vitamins and minerals (21 CFR Part 80) published in the FEDERAL REGISTER of January 19, 1973 (38 FR 2125 and 2152).

The proposed nutritional quality guideline for fortified hot breakfast cereals set forth below specifies an iron level of 8.1 milligrams per ounce on a dry uncooked basis. The Commissioner concludes that this level, which provides 45 percent of the U.S. RDA of iron per serving, will achieve the goal of maintaining fortified hot breakfast cereals as a good source of iron while exercising desirable restraint in fortification. The proposed levels for the remaining nutrients are those recommended by the NAS/NRC Committee.

Calcium is presently an optional nutrient in many cereal products. The NAS/NRC Committee concluded that there is sufficient evidence of possible deficiencies of dietary calcium and that this nutrient should be listed as mandatory. Generally, hot breakfast cereal products appear to be capable of serving as calcium manda- The proposal to make calcium mandatory is an attempt to preserve a desirable calcium-to-phosphorus ratio in the diet. Cereal grains commonly contain appreciable amounts of phosphorus.

The NAS/NRC Committee pointed out that there probably is an excess of phosphorus in the American diet. Accordingly, phosphorus was not included in the list of nutrients. It should be emphasized that phosphorus and other nutrients naturally present in amounts sufficient to meet labeling requirements may be listed on the label since these cereal products are covered by § 1.17 (21 CFR 1.17).

The NAS/NRC Committee did not recommend adding vitamin D to a cereal product because it does not meet the criteria for inclusion, which are discussed in the preamble to the proposed nutritional quality guideline for fortified ready-to-eat breakfast cereals published elsewhere in this issue of the FEDERAL REGISTER.

The Commissioner concurs that cereals generally are not suitable vehicles for vitamin D. This is especially true since its toxicity at higher levels has been established.

The NAS/NRC Committee did not recommend requiring a specific level of protein in this class of food product. It pointed out that different cereal grains contain varying amounts and qualities of protein. Further, it stressed the adverse effect of milling on the nutritional quality of the protein. The NAS/NRC Committee also pointed out that the surveys listed previously do not implicate protein deficiency as a public health problem in the United States. Breakfast cereals are not commonly viewed as major sources of protein.

For these reasons, the Commissioner concludes that protein should be included in the guideline only on an optional basis. Protein quality will be handled in this guideline as it is in § 1.17. The adult U.S. RDA is 65 grams if the protein efficiency ratio (PER) of the protein in the product is less than that of casein. This is expected to be the case for most cereal proteins that are not so badly damaged that their PER is below 20 percent of that of casein, in which case the protein cannot be listed as contributing to the percentage of the U.S. RDA for protein.

This guideline should not be construed as limiting the listing (in accordance with § 1.17) of nutrients naturally present in cereals. However, the three B Vitamins and two minerals, calcium and iron, listed in the guideline are the nutrients the Commissioner deems important in hot breakfast cereals. Claims that hot breakfast cereals have added nutritional value because of addition of nutrients at levels greater than those specified or with nutrients not listed in the guideline for fortified hot breakfast cereals are deemed inappropriate and the products they represent would have to bear the statement required by § 100.1(f), indicating that the addition of nutrients different from those listed in the guideline is regarded by the government as unnecessary and inappropriate.

The NAS/NRC Committee recommended establishment of 1 ounce (dry, uncooked form) as a serving size for breakfast cereals.

This recommendation is accepted, with the specification that the weight of the serving shall be calculated on a 15 percent moisture basis. This proposal does not apply to cereal products represented as "infant cereals". The Commissioner is considering a nutritional quality guideline for such products, and for the present he considers it reasonable to permit addition of iron and other nutrients to infant cereals at percentages of the U.S. RDA for infants similar to those in this guideline, as is currently common practice among manufacturers.

Elsewhere in this issue of the FEDERAL REGISTER the Commissioner is proposing general principles for the addition of nutrients to foods wherein the terms "fortification" and "fortified" are defined. That proposal specifies that no label claims regarding added nutrients will be permitted unless such addition(s) constitutes at least 10 percent of the U.S. RDA for the nutrient(s). Since hot breakfast cereals which meet the proposed guideline are "fortified" according to the definition in that proposal and since the nutrients are added at levels greater than 10 percent of the U.S. RDA, use of the term "fortified" for such products is proper.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201, 403, 701(a), 52 Stat. 1040–1042 as amended, 1047–1048 as amended, 1055 (21 U.S.C. 321, 343, 371(a)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120), it is proposed that Part 100 be amended by adding a new § 100.9 to Subpart B, as follows:

§ 100.9 Fortified hot breakfast cereals.

(a) In order to be eligible to bear the guideline statement set forth in § 100.1 (b), a fortified hot breakfast cereal described in paragraph (e) of this section shall contain the following vitamins and minerals in the amounts prescribed:

Nutrient	Per serving	
	Amount	Percent U.S. RDA
Protein (grams)	6.5	10
Thiamine (milligrams)	.38	25
Riboflavin (milligrams)	.23	15
Niacin (milligrams)	5.0	25
Calcium (milligrams)	150	15
Iron (milligrams)	8.1	45

(b) A serving shall be 1 ounce, dry, uncooked form (15 percent moisture).

(c) Protein is an optional nutrient for fortification. If it is added, the total quantity of protein present in the food

shall be at least at the level specified in paragraph (a) of this section.

(d) Protein content shall not be listed when the protein efficiency ratio (PER) is less than 20 percent of the PER of casein.

(e) The cereal products subject to this regulation are those manufactured for use as hot breakfast cereals. For the purposes of this section the term "cereal" includes food products made from the seeds of grains and similar plants and from oilseeds.

(f) A hot breakfast cereal which meets this guideline may bear the term "fortified" as part of its name.

(g) A hot breakfast cereal that contains 50 percent or more of the U.S. RDA value of one or more added vitamins or minerals per serving is a dietary supplement subject to the requirements of § 80.1 of this chapter. Any such product shall conform to the labeling requirements of § 1.17(c) of this chapter and shall comply in all other respects with the requirements of § 80.1 of this chapter.

(h) The provisions of this section are not applicable to a hot breakfast cereal product represented as an infant cereal.

Interested persons may, on or before August 13, 1974, file with the Hearing Clerk, Food and Drug Administration, Rm. 6–86, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: June 7, 1974.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.74–13474 Filed 6–13–74;8:45 am]

[21 CFR Part 100]

FORTIFIED READY-TO-EAT BREAKFAST CEREALS

Proposed Nutritional Quality Guideline

In the FEDERAL REGISTER of March 14, 1973 (38 FR 6969), the Commissioner of Food and Drugs promulgated a procedure and general principles for the establishment by regulation of nutritional quality guidelines for foods.

The Commissioner had earlier contracted with the National Academy of Sciences for assistance in identifying and defining the important classes of foods for which such nutritional quality guidelines should be established and in providing proposed nutrient compositions for them which would be in the best interest of the public health. The recommendations of the Committee on Food Standards and Fortification Policy of the National Academy of Sciences/National Research Council (the NAS/NRC Committee) for fortified breakfast cereals have been received by the Commissioner. A copy of this report is on public display in the office of the Hearing Clerk, Food and Drug Administration, Rm. 6–86, 5600 Fishers Lane, Rockville, MD 20852.

The NAS/NRC Committee recognized that breakfast cereals now on the market vary from those containing no added nutrients to those to which are added as many as nine vitamins plus iron, calcium, and phosphorus, at levels ranging from token amounts to the entire day's requirements of the nutrients in a single serving. This proposal is designed to foster breakfast cereals having appropriate amounts of the proper nutrients as determined by the NAS/NRC Committee. Those ready-to-eat breakfast cereals which meet the proposed nutritional quality guideline may bear a statement that the product "provides nutrients in amounts appropriate for this class of food as determined by the U.S. Government", as provided in § 100.1(b) (21 CFR 100.1(b)).

No differentiation between ready-to-eat breakfast cereals and hot breakfast cereals, or among such products prepared from various cereal grains, was made in the NAS/NRC Committee's recommendation. However, consumer usage of enriched farina (as discussed in the preamble to the Commissioner's proposal to amend the identity standard for enriched farina (21 CFR 15.140) published elsewhere in this issue of the FEDERAL REGISTER) and other hot breakfast cereal products as a source of iron for infants, young children, and aged persons is sufficient cause to amend the standard of identity for enriched farina and to develop a separate nutritional quality guideline for fortified hot breakfast cereals, also published elsewhere in this issue of the FEDERAL REGISTER.

Three different principles considered by the NAS/NRC Committee for selecting nutrients to be included in fortified breakfast cereals were (1) nutrients present in whole cereal grains in significant amounts, (2) nutrients included in the enrichment standards for cereal grains, and (3) nutrients for which there is evidence of deficiency in the U.S. diet.

The NAS/NRC Committee decided that, in general, whole cereal grains contribute to the diet significant amounts of protein, thiamine, niacin, vitamin B_6, iron, magnesium, zinc, and copper. Nutrients included in standards for enriched flour include thiamine, riboflavin, niacin, iron, and calcium. Vitamin D has been excluded from the list of nutrients in this guideline because of its established toxicity at higher levels and because it would be expected to be contributed by the milk with which the cereal normally is eaten. Copper has been excluded from the list, since it is very difficult to obtain a diet of common food that is deficient in copper.

Information on nutrients for which there are established deficiencies is limited. Based on the data from the Ten-State Nutrition Survey and the 1965 USDA Food Consumption Survey (copies of these documents are on public display in the office of the Hearing Clerk), the NAS/NRC Committee concluded there was a risk of deficiencies of vitamin A, vitamin B_6, folic acid, calcium, and iron in the U.S. diet.

The NAS/NRC Committee recommended that zinc and magnesium be listed as optional until the technical feasibility of adding the amounts specified has been established. The Commissioner accepts this recommendation.

Manganese was included in the guideline recommendation of the NAS/NRC Committee as an optional nutrient. A U.S. Recommended Daily Allowance (U.S. RDA) value has not been set for manganese because of the lack of knowledge on intake levels mentioned by the NAS/NRC Committee, and, on that basis, the Commissioner concludes that listing manganese as a required nutrient is premature at this time.

Calcium is presently an optional nutrient in many cereal products. The NAS/NRC Committee concluded that there is sufficient evidence of possible deficiencies of dietary calcium that this nutrient should be listed as mandatory. Generally, ready-to-eat breakfast cereal products appear to be capable of serving as calcium carriers. The proposal to make calcium mandatory is an attempt to preserve a desirable calcium-to-phosphorus ratio in the diet.

The NAS/NRC Committee concluded that phosphorus should not be included in the list of required nutrients since there already is too large an amount of phosphorus in the U.S. diet. Further, it appears desirable to minimize the addition of phosphates within technological limits. The NAS/NRC Committee also excluded biotin from the list of added nutrients (although it is an essential nutrient) because problems of deficiency can be observed only under unusual circumstances. It should be noted that phosphorus, biotin, and other nutrients naturally present in amounts sufficient to meet labeling requirements may be listed on the label, subject to nutrition labeling (21 CFR 1.17).

The NAS/NRC Committee suggested that iodine should be present at the level equivalent to that achieved by using iodized salt. However, although this nutrient does meet one of the three criteria for inclusion in a breakfast cereal, the Commissioner concludes that the use of various chemical forms of iodine in cereals needs further study since there may be serious organoleptic and stability problems. For this reason, the Commissioner concludes that iodine should not be listed as a guideline nutrient for cereals at this time.

The NAS/NRC Committee used a mean Recommended Daily Dietary Allowance in the development of its guidelines. The Food and Drug Administration has established the U.S. RDA values for purposes of labeling, and these will be used in developing nutritional quality guidelines. With a few exceptions, the U.S. RDA values are the highest values listed for each nutrient in the NAS/NRC tables of Recommended Daily Dietary Allowances. Derivation and use of the U.S. RDA values are discussed in detail in the FEDERAL REGISTER of January 19, 1973, in the preambles to § 1.17, Nutrition Labeling (38 FR 2125); §§ 125.1, 125.2, 125.3, Special Dietary Foods (38 FR 2152); and § 80.1, Dietary

Supplements of Vitamins and Minerals (38 FR 2152), and in the FEDERAL REGISTER of August 2, 1973, §§ 125.1, 125.2, 125.3, Special Dietary Foods (38 FR 20708). A standard reference value is required to avoid consumer confusion and undue labeling costs. Therefore, this nutritional quality guideline is based on the U.S. RDA table listed in § 1.17 (21 CFR 1.17). The amounts of nutrients present in a fortified ready-to-eat breakfast cereal shall be described in its labeling as required by § 1.17.

The NAS/NRC Committee did not recommend requiring a specific level of protein in this class of food product. The NAS/NRC Committee pointed out that different cereal grains contain varying amounts and qualities of protein. Further, it stressed the adverse effect of milling on protein quality. The NAS/NRC Committee also pointed out that the surveys listed previously do not implicate protein deficiency as a public health problem in the United States. Breakfast cereals are not commonly viewed as major sources of protein. For these reasons, the Commissioner concludes that protein should be included in the guideline only on an optional basis.

The NAS/NRC Committee recommended a weighting factor for the protein present related to the protein efficiency ratio (PER). The difficulties and costs of such determinations, together with the questions concerning their application in human nutrition, are discussed in detail in the two preambles to the nutrition labeling regulation (21 CFR 1.17) published in the FEDERAL REGISTER of January 19 and March 14, 1973 (38 FR 2125 and 6951). Protein quality will be handled in this guideline as it is in § 1.17. The adult U.S. RDA is 65 grams if the PER of the protein in the product is less than that of casein. This is expected to be the case for most cereal proteins that are not so badly damaged that their PER is below 20 percent of that of casein. In accordance with § 1.17(c)(7)(ii)(*b*), the protein content of products with PER values below 20 percent of that of casein cannot be considered as providing any part of the U.S. RDA.

The NAS/NRC Committee advised that most cereals are eaten with milk by a wide variety of people and that 1 ounce of cereal could logically be considered a serving. The Commissioner has encouraged industry to establish uniform, reasonable serving sizes for the purposes of nutrition labeling, because diversity in such sizes will make nutrient comparisons among competing products impossible. The Commissioner concludes that a reasonable serving size is 1 ounce, except that a serving size for a single service container shall be the amount in the container.

The NAS/NRC Committee commented further that a reasonable amount of milk served with a 1 ounce serving of cereal would be about 4 fluid ounces. The Commissioner agrees. As provided in § 1.17, nutrition labeling may contain a column describing the nutrient content of a serving of cereal plus a specified amount of milk (and sugar). If such a second column is listed, the amount and type of milk (and the amount of sugar) must be specified. The Commissioner proposes to specify 4 fluid ounces of milk for the purposes of such labeling.

The protein supplied by the whole milk is obviously capable of meeting or exceeding the PER of casein. Hence, the U.S. RDA for the protein in the milk is 45 grams. The NAS/NRC Committee suggested that, due to normal consumption patterns, the PER value of major interest is that of the mixture of cereal and milk. Although this is certainly true, it is difficult to specify or enforce from a compliance viewpoint.

For the purposes of nutrition labeling, a method to obviate extensive PER determination is specified. The percentage of the U.S. RDA for protein supplied by a specified mixture of cereal and milk will be determined by adding together the percentages of the U.S. RDA for protein provided by the cereal and milk alone. The U.S. RDA of the cereal protein will normally be 65 grams and the U.S. RDA of the milk protein will be 45 grams. It is realized that PER values commonly are not additive. However, to compute the percent of the U.S. RDA of the total amount of protein present in cereal plus milk using only the PER of the milk protein is not reasonable, since to do so would permit claims of a greater PER value for the cereal protein than is actually present.

The NAS/NRC Committee expressed the belief that "presweetened cereals" result in undue dilution of cereal nutrition with sugar. The consumption of sugar in the United States has increased over an extended period of time. However, considerable data show that presweetened cereals contribute only a small amount to this overall consumption and in some cases only replace sugar that would be added by the consumer. ("Food Consumption, Prices, and Expenditures," Supplement for 1972 to Agricultural Economic Report No. 138, USDA, Economic Research Service. "A Study of Breakfast and Cereal Nutrition" presented by General Mills, Inc. to the Food and Drug Administration, September 7, 1973. Copies of these documents are on public display in the office of the Hearing Clerk). It appears unreasonable, therefore, to restrain fortification of such products by excluding them from this guideline when they are used in a fashion very similar to other breakfast cereals. Accordingly, this section is applicable to presweetened cereals.

A major purpose of nutritional quality guidelines is to prevent nutrient "horsepower" races—the essentially useless addition of nutrients to a food to give a false appearance of nutritional superiority. Accordingly, while the regulation does not restrict the nutrients that may be listed if naturally present, 21 CFR 100.1(f) requires a label statement explaining that the addition of nutrients different from those listed in the guideline is regarded by the government as unnecessary and inappropriate. Consumers who are interested in such differences because of specific needs or beliefs can readily make their choice of product by reading the information panel on the label. For example, if a fortified breakfast cereal naturally contains 6 percent of the U.S. RDA of vitamin E per serving, this nutrient content may be listed on the information panel.

A ready-to-eat breakfast cereal to which is added any nutrient at a level which falls within the dietary supplement range established in § 80.1 (21 CFR 80.1) is subject to the provisions of that section, and thus is not subject to the proposed nutritional quality guideline for this class of food.

Dietary supplements that are prepared in the form of breakfast cereals shall conform to the labeling established in § 1.17(c) including the order for listing vitamins and minerals and the location of the information panel established in §§ 1.17(c)(7)(iv) and 1.8d. They shall comply in all other respects with the requirements of 21 CFR 80.1.

The NAS/NRC Committee pointed out that there are several cereals with little or no vitamin or mineral fortification but which are good sources of some vitamins and trace minerals. This proposal is not designed to restrict production of breakfast cereals with naturally occurring amounts of vitamins and minerals lower or higher than those contained in this proposed guideline, provided they are labeled in accordance with applicable sections of the Federal Food, Drug, and Cosmetic Act. Cereals containing added nutrients or for which nutrition claims are made shall conform with the full requirements of § 1.17.

Elsewhere in this issue of the FEDERAL REGISTER the Commissioner is proposing general principles for the addition of nutrients to foods wherein the terms "fortification" and "fortified" are defined. That proposal specifies that no label claims regarding added nutrients will be permitted unless such addition(s) constitutes at least 10 percent of the U.S. RDA for the nutrient(s). Since ready-to-eat breakfast cereals which meet the proposed guideline are "fortified" according to the definition contained in that proposal, and since the nutrients are added at levels greater than 10 percent of the U.S. RDA, use of the term "fortified" for such products is proper.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201, 403, 701(a), 52 Stat. 1040–1042 as amended, 1047–1048 as amended, 1055 (21 U.S.C. 321, 343, 371(a))), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120) it is proposed that Part 100 be amended by adding a new section to Subpart B, as follows:

§ 100.10 Fortified ready-to-eat breakfast cereals.

(a) In order to be eligible to bear the guideline statement set forth in § 100.1 (b), a ready-to-eat breakfast cereal described in paragraph (d) of this section shall contain the following vitamins and minerals in the amounts prescribed:

Nutrient	Per serving	
	Amount	Percent U.S. RDA
Protein (grams)	6.5	10
Vitamin A (IU)	1,250	25
Thiamine (milligrams)	.38	25
Riboflavin (milligrams)	.26	15
Niacin (milligrams)	5.0	25
Calcium (milligrams)	150	15
Iron (milligrams)	4.5	25
Vitamin B_6 (milligrams)	.5	25
Folic acid (μg)	.1	25
Magnesium (milligrams)	100	25
Zinc (milligrams)	3.8	25

(b) A serving shall be 1 ounce, except that a serving for a single service container shall be the amount in the container. A serving of milk with ready-to-eat breakfast cereal shall be 4 fluid ounces.

(c) Protein, magnesium, and zinc are optional nutrients for fortification. If they are added, the total quantities present in the food shall be at least at the levels specified in paragraph (a) of this section.

(d) Protein content shall not be listed when the protein efficiency ratio (PER) is less than 20 percent of the PER of casein.

(e) The cereal products subject to this regulation are those manufactured for use as ready-to-eat breakfast cereals. For the purposes of this section the term "cereal" includes food products made from the seeds of grains and similar plants and from oilseeds.

(f) A ready-to-eat breakfast cereal which meets this guideline may bear the term "fortified" as part of its name.

(g) A ready-to-eat breakfast cereal that contains any nutrient at a level which falls within the dietary supplement range established in § 80.1 of this chapter is subject to the requirements of § 80.1 and is not subject to this section. Any such product shall conform to the labeling requirements of § 1.17(c) and shall comply in all other respects with the requirements of § 80.1.

(h) When the dual declaration of nutrient content of cereal plus milk, provided in § 1.17(d)(2) of this chapter, is used in the nutrition labeling of a product which meets this guideline, the percentage of the U.S. RDA for protein provided by the cereal plus milk mixture shall be the sum of the percentage of the U.S. RDA for protein provided by the cereal alone and the percentage provided by the milk alone.

(i) The provisions of this section are not applicable to a ready-to-eat breakfast cereal product represented as an infant cereal.

Interested persons may, on or before August 13, 1974, file with the Hearing Clerk, Food and Drug Administration, Rm. 6–86, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: June 7, 1974.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.74–13472 Filed 6–13–74;8:45 am]

[21 CFR Part 100]

GENERAL PRINCIPLES GOVERNING THE ADDITION OF NUTRIENTS TO FOODS

Notice of Proposed Rule Making

The Commissioner of Food and Drugs has promulgated a series of regulations related to the nutritional quality of foods in recent months. The regulations have included nutrition labeling under § 1.17 (21 CFR 1.17), fat, fatty acid, and cholesterol labeling under § 1.18 (21 CFR 1.18), imitation foods under § 1.8(e) (21 CFR 1.8 (e)), special dietary foods under Part 125 (21 CFR Part 125), nutritional quality guidelines under Part 100 (21 CFR Part 100), dietary supplements of vitamins and minerals under § 80.1 (21 CFR 80.1), and amino acid addition to foods under § 121.101 (21 CFR 121.101). Other existing standards of identity permit or require addition of vitamins, minerals, and protein to foods in order to improve the nutritional quality of the product, e.g., enriched flour under § 15.10 (21 CFR 15.10).

During the development of regulations related to nutrition, it became apparent that there is a need to define and publish the principles governing the addition of vitamins, minerals, and protein to food.

The Commissioner concludes that a separate standard of identity for each food to which a vitamin, mineral, and/or protein may properly be added is neither practicable nor appropriate. The Commissioner has also determined that a single standard of identity listing all foods to which a vitamin, mineral, and protein may properly be added, is unnecessarily inflexible in light of developing knowledge about nutrition. Accordingly, in the FEDERAL REGISTER of January 19, 1973 (38 FR 2153) the Commissioner announced his intention to hold in abeyance the portion of the 1968–1970 special dietary food regulation hearings relating to vitamin- and mineral-fortified foods, identity, and label statements, under § 80.2, pending experience under nutritional quality guidelines.

The general principles for the establishment of such nutritional quality guidelines were proposed in the FEDERAL REGISTER of December 23, 1971 (36 FR 24822) and promulgated in the FEDERAL REGISTER of March 14, 1973, (38 FR 6969). The Commissioner has concluded that it is now appropriate to establish general principles governing the addition of vitamins, minerals, and protein to food, which will serve as the basis on which the Food and Drug Administration will permit such nutrient addition in the future.

The addition of vitamins and minerals to foods was first undertaken as a public health measure to prevent the development of deficiency diseases that afflicted large segments of the public. As the causes of such diseases as goiter and rickets were identified, the addition of specific nutrients to food was recommended. The success of this program has been widely recognized and acclaimed. The addition of iodine compounds to salt over fifty years ago, which has ended a widespread goiter problem, is a good example of consumer benefits from this type of program.

The addition of nutrients to foods has been evaluated by many public health and nutrition authorities. It is generally concluded that such programs have provided a safeguard in national diets and have been effective in reducing the prevalence of deficiency diseases in many countries. Such programs remain valuable today, provided sufficient information is available to identify the nutrition problem, to define affected population groups, and to designate suitable foods to act as vehicles for the added nutrients.

The basic principle that dietary deficiency disease can be prevented by appropriate addition of nutrients to foods has been best described in "Improvement of Nutritive Quality of Foods," a joint policy statement by the Food and Nutrition Board of the National Academy of Sciences–National Research Council (NAS/NRC) and the Council on Foods and Nutrition of the American Medical Association (AMA) published in the *Journal of the American Medical Association*, 205:868–869, Sept. 16, 1968. This statement has been retained in the more recent report, "Improvement of the Nutritive Quality of Foods, General Policies" of the Council on Foods and Nutrition, published in the *Journal of the American Medical Association*, 225:1116–1118, August 27, 1973, and in the statement, "General Policies in Regard to Improvement of Nutritive Quality of Foods," prepared by the Food and Nutrition Board of the NAS/NRC, released on August 23, 1973. Copies of these statements are on file with the Hearing Clerk. The practical application of the principles stated by these two groups is given in the following quotation from the 1968 statement:

> The availability and low cost of nutrients produced industrially and the advances in food technology have enhanced the potential for the improvement of existing foods and for the formulation of new foods. Enrichment, fortification, and restoration of nutritional value of certain foods have been endorsed by the Council on Foods and Nutrition and the Food and Nutrition Board. Specifically, the following practices in the United States continue to be endorsed: The enrichment of flour, bread, degerminated corn meal, corn grits, whole grain corn meal, and white rice (with thiamine, riboflavin, niacin, and iron); the retention or restoration of thiamine, riboflavin, niacin, and iron in

processed food cereals; the addition of vitamin D to milk, fluid skim milk, and nonfat dry milk; the addition of vitamin A to margarine, fluid skim milk, and nonfat dry milk; and the addition of iodine to table salt. The protective action of fluoride against dental caries is recognized and the standardized addition of fluoride to water is endorsed in areas in which the water supply has a low fluoride content.

The Commissioner is aware that permitting the addition of nutrients to foods solely on the basis of an identified deficiency disease, or of the probability that it will develop because of a basic nutrient deficiency in the food supply, would be unduly restrictive. With the increased use of convenience foods, fabrication of foods from new ingredients, and substitute foods, there is a need to maintain the nutritional quality of diets when there are changes in food patterns. When evidence of a substantial change in food consumption patterns has occurred which results in a less satisfactory nutrient intake in the population, consideration must be given to application of the principles of fortification to improve the diet.

A new § 80.2, to establish a standard of identity for all vitamin- and mineral-fortified foods, was published in the FEDERAL REGISTER on June 18, 1966 (31 FR 8521). The order was subsequently stayed because of objections and requests for public hearings in an order published December 14, 1966 (31 FR 15730). A further order was subsequently published in the FEDERAL REGISTER of April 8, 1967 (32 FR 5736), amending § 80.2 to add additional classes of food. A hearing was convened in May 1968 and continued for two years, closing in May 1970. Extensive oral and documentary evidence was presented with respect to the food fortification policy enunciated in § 80.2.

In December 1969, a White House Conference on Food, Nutrition and Health was convened. The Report of the Conference reflected a consensus that nutrition information and food consumption patterns are too dynamic to be written down in, or governed by, inflexible rules, but that the Food and Drug Administration should establish standards of nutritional quality for all foods used as a significant part of the diet to assure a minimal nutrient content in the diet.

After reviewing the portion of the special dietary food hearings concerning fortified foods and the recommendations of the White House Conference on Food, Nutrition and Health, the Commissioner concluded that it would be in the public interest to develop regulations for fortified foods utilizing the approach of establishing nutritional quality guidelines for certain classes of foods, including those to which vitamins, minerals, and protein may be added, in lieu of establishing standards of identity as originally adopted in § 80.2. The Commissioner therefore added a new Part 100 for nutritional quality guidelines for foods, and established the first nutritional quality guidelines for precooked frozen convenience "heat and serve" dinners.

The Commissioner has also considered the relation of "imitation" foods to nutritional quality. In the FEDERAL REGISTER of January 19, 1973 (38 FR 2138), a proposal was published to define "imitation" food in terms of nutritional content. The proposal stated that nutrients could be added to substitute foods in order to achieve nutritional equivalence. The Commissioner published an order in the FEDERAL REGISTER of August 2, 1973 (38 FR 20702), establishing § 1.8(e) which defined "imitation" and established the criteria for determining nutritional equivalence. The preamble to the order stated that vitamin and mineral additions to substitute foods would be permitted in order to achieve nutritional equivalence but cautioned against excessive fortification.

The Food and Nutrition Board of the NAS/NRC and the Council on Foods and Nutrition of the AMA have also discussed the need for restoring vitamins and minerals to replace those lost in the processing of foods. The August 23, 1973, statement from the NAS/NRC states in part:

> The appropriate selection of a wide variety of conventional foods is important in assuring adequate intake of all essential nutrients. It is, of course, desirable that foods having undergone some form of post-harvest processing contain the variety and amounts of essential nutrients that were present at significant levels in the raw, preprocessed food. A significant level of a nutrient is considered to be 5 percent or more of the RDA of that nutrient in an average serving. Restoration of nutrients lost in the processing of foods has been recognized for many years as an appropriate method for improving their nutritional value. Under circumstances where restoration is undertaken through the addition of nutrients as specific chemical entities, it is important that all essential nutrients present at significant levels in the original preprocessed food be restored to the extent that is technically feasible. The nutrient level achieved through restoration should be 1.0–1.5 times preprocessed levels. The principle of extensive restoration is of special importance when a label claim for the content of an added nutrient is made.

The basic concept adopted by both organizations is to restore significant nutrient levels of processed foods to the levels present in the fresh unprocessed food. An uncontrolled restoration could result in the addition of trivial amounts of nutrients, giving rise to misleading promotional claims but providing no significant benefit to consumers.

The Canadian Food and Drug Directorate, in its "Trade Information Letter" No. 351, April 28, 1971, proposed a procedure to allow controlled restoration of nutrients lost in the course of manufacturing, similar to the approach proposed by the AMA and the NAS/NRC. It states that vitamins, minerals and protein added to traditional foods should be present in amounts related to the purpose of the addition, e.g., to replace those nutrients lost in the course of good manufacturing practice, if the amount originally present provided at least 10 percent of the daily requirement of these nutrients in a reasonable daily intake of the food, the amount added should compensate for that lost in processing. The Canadian government has been applying this guideline since 1971.

The concept of adding nutrients to foods when such nutrients are lost in processing, only when the foods are recognized as significant sources of the nutrients, appears to be one acceptable approach.

However, the Commissioner concludes that restoration of measurable nutrient loss for any processed food is more reasonable and has adopted this approach in the proposal. The use of nutrition labeling under § 1.17 requires that vitamin and mineral levels be listed at 2-percent intervals between 2 and 10 percent of the United States Recommended Daily Allowance (U.S. RDA) for each nutrient. The level of 5 percent of the U.S. RDA proposed by the AMA Council on Foods and Nutrition and the NAS/NRC Food and Nutrition Board to determine if a food is a significant source of a nutrient falls outside the labeling increments. Because 2 percent of the U.S. RDA is sufficiently important to justify labeling increments at this level, the Commissioner proposes 2 percent of the U.S. RDA as the minimum loss of a nutrient during processing if restoration is to be permitted. Thus, restoration of trivial amounts of nutrients will not be permitted, since such a practice would be misleading and deceptive.

The Commissioner also proposes to permit the addition of nutrients to certain classes of foods if addition of the nutrient is necessary to raise the nutritional quality of the food up to the nutritional level appropriate for that class of food based upon the best available scientific data on food consumption, nutrition needs, and dietary habits.

The White House Conference on Food, Nutrition and Health recommended vitamin and mineral fortification based on caloric content. The NAS/NRC Committee which developed the initial nutritional quality guideline reports also suggested that nutrient levels in some foods should be related to the caloric contribution of the food. Following such a pattern, nutrient additions would be controlled by restricting the level of any added nutrients to the percentage of the U.S. RDA equal to the caloric contribution of the food to a daily calorie standard. The Commissioner proposes to set the daily calorie standard at 2800 kilocalories. Thus, a food which contributes 280 kilocalories per serving (10 percent of the daily calorie standard) could have vitamins, minerals, and protein added per serving to a level equal to 10 percent of the U.S. RDA. This approach will prevent irrational fortification or fortification to unduly high levels or levels which would make the products dietary supplements. The AMA Council on Foods and Nutrition, in its statement of August 27, 1973, outlined its position as follows:

> Nutrient density is an expression of nutrient content in terms of caloric value of a serving of food as related to a standard such as the RDA * * * for nutrients and calories. For example, a serving containing 280 kilocalories might be referred to a calorie standard of 2,300 kilocalories/day. In this instance, the food represents 10 percent of the calorie

value of the standard and should be expected to contain this percentage of each of the nutrients in the standard. If a given nutrient is naturally present in an amount equal to three quarters or more of that percentage, no further adjustment is needed.

A similar concept has been proposed using protein content as the food component for establishing the role of the food in the diet. The mechanism for control of vitamin and mineral additions would be similar to that when calorie content is used as a basis for control. When protein is used, protein-free products are eliminated from consideration, even when they provide significant caloric contributions, and no basic standard is provided for the addition of protein to a food. However, when calories are used as the basis for comparison, protein can be considered as a nutrient and added when appropriate.

The Commissioner proposes that the concept of relating vitamin, mineral, and protein content to caloric contribution either for the addition of nutrients to foods, or for establishing nutritional quality, be included in the general regulation regarding the addition of nutrients to foods. A careful review of the procedure as proposed by the White House Conference and the NAS/NRC Committee developing the nutritional quality guidelines and in the AMA Council on Foods and Nutrition statement indicates that it can be used not only in controlling the addition of nutrients to foods, but also as a means for establishing a basic concept of nutritional quality for fabricated foods.

Thus, the Commissioner proposes to allow the addition of nutrients to foods using the "balanced" concept of adding nutrients in relation to calories. Such nutrient addition would not be appropriate, however, where the desirable nutrient addition or composition of the food has already been established by a nutritional quality guideline or a food standard, and the proposal therefore excludes these foods from this form of fortification. Thus, white bread would be required to be enriched pursuant to the existing food standard, if any nutrients are added, and could not be fortified under the balanced nutrient approach. Manufacturers wishing to use the balanced nutrient approach to fortification must carefully consider the criteria established in the regulation. Where appropriate, consumers or manufacturers may also petition the Commissioner to establish a nutritional guideline or a standard of identity.

For the purposes of nutrient addition to achieve "balanced" nutrition, the Commissioner proposes that a caloric level of 2800 kilocalories be set as a daily standard, and that the vitamin and mineral levels be those established under § 1.17(c)(7)(iv). The protein levels will be the same as those established under § 1.17(c)(7)(ii)(a). The protein levels to be used to calculate the protein per 100 kilocalories would be 65 grams for protein with a protein efficiency ratio (PER) less than casein but more than 20 percent that of casein and 45 grams for protein with a PER equal to or greater than that of casein. The PER shall be determined by the appropriate method in "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th edition, (1970).[1] A table giving the nutrient levels per 100 kilocalories included in the proposal is as follows:

Nutrient	Unit of measurement	Adults and children over 4 yr	
		U.S. RDA	Per 100 kcal
Protein	Grams	[1] 65.0	2.32
Do	do	45.0	1.61
Vitamin A	IU	5,000.0	179
Vitamin C	Milligrams	60.0	2.14
Thiamine	do	1.5	.054
Riboflavin	do	1.7	.061
Niacin	do	20.0	.72
Calcium	Grams	1.0	.036
Iron	Milligrams	18.0	.64
Vitamin D	IU	400.0	14.3
Vitamin E	do	30.0	1.07
Vitamin B$_6$	Milligrams	2.0	.071
Folic acid	do	.4	.014
Vitamin B$_{12}$	μg	6.0	.21
Phosphorus	Grams	1.0	.036
Iodine	μg	150.0	5.36
Magnesium	Milligrams	400.0	14.3
Zinc	do	15.0	.54
Copper	do	2.0	.071
Biotin	do	.3	.011
Pantothenic	do	10.0	.357

[1] If the protein efficiency ratio of protein is equal to or better than that of casein, U.S. RDA is 46 g.

In the past, the addition of a vitamin or mineral to a food has resulted in the food being defined as a "special dietary food." This approach was adopted to ensure that such foods would contain specific label information about the particular nutrient(s) involved, pursuant to regulations promulgated in 21 CFR Part 125. Virtually all of the foods previously categorized as special dietary foods for purposes of requiring nutrient labeling have been intended for consumption by the general population and not by any particular small segment of it. With the development of nutrition labeling under § 1.17, it is no longer necessary to regulate nutrient labeling of these general purpose foods under the provisions of the law relating to special dietary foods.

For some products, general nutrition labeling under § 1.17 is inappropriate and very specific special dietary food labeling under 21 CFR Part 125 has been retained. These foods were exempted from § 1.17 in the final regulation. Such exempted foods include certain infant foods for which separate labeling has been promulgated in § 125.5; dietary supplements of vitamins and minerals, subject to a standard of identity in § 80.1; any food intended for use as the sole item of the diet, for which specific special dietary food labeling, including in some cases amino acid composition, is appropriate under 21 CFR Part 125; and foods represented for use solely under medical supervision to meet nutritional requirements in specific medical conditions, such as foods for the dietary management of inborn errors of metabolism, for which specific special dietary food labeling is also more appropriate under 21 CFR Part 125. In each of these instances, the broad approach adopted for nutrition labeling, which is clearly desirable for general consumer use, is inappropriate because of the need for more detailed and specific information and because the type of product involved is more readily susceptible to precise quality control of the nutrient levels.

Thus, the addition of a vitamin, mineral, or protein to food, unless included in one of the above exemptions, will not result in that food being considered a special dietary food for labeling purposes. Such addition of a nutrient will instead require full nutrition labeling under § 1.17.

Over the years, several terms have been used to describe the different purposes for addition of nutrients to foods, i.e., enrichment, restoration, and fortification.

The term "enrichment" usually is defined as the addition of one or more nutrients to a food in order to increase the consumption of those nutrients by the general population or a defined segment of the population. The nutrients added to the food are higher levels of those nutrients already present in the food. The best example of enrichment is bread and flour. The term enrichment has often been incorporated into the name of the food to which the nutrients have been added, e.g., "enriched bread," "enriched flour."

"Restoration" is the addition of nutrients to conventional foods in order to restore nutrients lost during processing. The level of the restored nutrient is approximately the same as is present naturally in the product.

"Fortification" has been used to denote the addition of one or more nutrients to a food whether or not they are naturally present. The terms "vitamin added" or "with added vitamins and minerals" as well as the term "fortified" have, at times, been used to identify fortified products. This definition overlaps that given to "enrichment," and would permit the same food to be labeled as "enriched" or "fortified." This could result in consumer confusion.

The Commissioner proposes to limit the use of the word "fortified" to those situations where nutrients are added to a food which does not naturally contain those nutrients. Since the addition of several nutrients to a food can occur, the addition of any one nutrient, not naturally present in the food, shall require that the term "fortified" be used even if other nutrients are added which are naturally present in the food.

While the terms stated above ("enriched," "restored," "fortified") can be defined so they have specific meanings, they have often been used interchangeably and thus the consumer probably accepts all as indicating simply that the nutritional quality has been improved by the addition of a nutrient.

The Commissioner proposes to define these terms as set forth above so that

[1] Copies may be obtained from: Association of Analytical Chemists, P.O. Box 540, Ben Franklin Station, Washington, DC 20044.

they will be used properly in labeling and interested persons will be able to distinguish between them.

The Commissioner emphasizes that the publication of this proposed regulation on the addition of nutrients to foods is not intended to encourage the industry to put vitamins, minerals, or protein into every food. The addition of a nutrient to a food must conform to the principles in the proposed regulation, and provide consumers with reasonable benefit without misleading them into believing that the food with added nutrients will ensure a complete diet. The proposed regulation, therefore, provides that, if the addition of a nutrient(s) to a food is contrary to the regulation, the food to which the nutrient(s) is added is required to bear a prominent statement that the nutrient(s) added has been determined by the U.S. Government to be unnecessary and inappropriate.

The Commissioner also proposes to amend § 100.1 to provide that any food which would otherwise be required to be labeled with the statement specified in § 100.1(f) will not be required to be so labeled if the nutrient(s) is added to the product in accordance with § 1.8(e) of this chapter to avoid being an imitation.

In order to prevent labeling claims for the addition of measurable amounts of nutrients to foods which do not reach the level of substantial nutritional "significance," the Commissioner proposes to prohibit claims concerning the addition of any nutrient for purposes of enrichment, fortification, or restoration, or the balanced nutrition concept unless such addition is equal to or in excess of 10 percent of the U.S. RDA per serving. Also, in order to prevent labeling claims which might result in a substitute food being represented as superior to the food which it resembles because of nutrients added to prevent nutritional inferiority, the proposed regulation prohibits labeling claims concerning the addition of nutrients to such foods.

These two prohibitions apply only to claims relating directly to the addition of nutrients, and in no way prohibit claims on the total nutrient content of the food itself. Thus, the label for a product to which less than 10 percent of the U.S. RDA of a nutrient is added could not declare the product to be "fortified" or "enriched" or "restored," or otherwise state or imply that nutrients have been added. On the other hand, there would be no prohibition for label statements on such products which accurately claim that the product contains a specified amount of the nutrient, e.g., "contains 6 percent of the U.S. RDA of _____".

In order to make it possible to make nutrient claims for foods which do contain at least 10 percent or more of the U.S. RDA of nutrients added for the purposes of enrichment, restoration, or fortification, the Commissioner proposes to amend paragraph (d) to allow claims to be made on the labels of foods which comply with the guidelines established in Subpart B.

The section on general principles of the regulations on nutritional quality guidelines, § 100.1 (21 CFR 100.1), does not state specifically whether nutritional quality guidelines apply only to nonstandardized foods or to standardized foods as well. In the preamble to the proposal to establish a nutritional quality guideline for breakfast beverage products, published elsewhere in this issue of the FEDERAL REGISTER, it is stated that a breakfast beverage product which meets the vitamin C requirements of an applicable standard of identity may bear the guideline statement provided in § 100.1 (b).

In order to prevent misinterpretation of the applicability of nutritional quality guidelines to standardized foods, the Commissioner proposes to amend § 100.1 (b) and (c) to provide that a food which contains a vitamin(s) or mineral(s) added for nutritional purposes, in accordance with the provisions of a standard of identity, may bear the statement provided in § 100.1(b). When the provisions for vitamin or mineral content of a standard of identity differ from the nutrient levels of an applicable nutritional quality guideline in Subpart B of Part 100, a proposal to amend the standard of identity to conform with the nutritional quality guideline will be published for comment.

Pertinent background information to which reference has been made as well as other information on which the Commissioner relies to support this proposal is on public display at the office of the Hearing Clerk.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201, 403, 701(a), 52 Stat. 1040–1042 as amended, 1047–1048 as amended, 1055 (21 U.S.C. 321, 343, 371(a))) and under authority delegated to him (21 CFR 2.120), the Commissioner proposes to amend Subpart A of Part 100 in § 100.1 by revising paragraphs (b), (c), (d), and (f) and by adding new paragraphs (g), (h), (i), and (j), to read as follows:

§ 100.1 General principles.

* * * * *

(b) Labeling for a product which complies with all of the requirements of the nutritional quality guideline established for its class of food or of a food standard promulgated under section 401 of the act that prescribes the nutrient additions to the food may state "This product provides nutrients in amounts appropriate for this class of food as determined by the U.S. Government", except that the words "this product" are optional. This statement, if used, shall be printed on the principal display panel and may also be printed on the information panel, in letters not larger than twice the size of the minimum type required for the declaration of net quantity of contents by § 1.8b of this chapter. Labeling of noncomplying products may not include any such statement or otherwise represent, suggest, or imply the product as being, in whole or in part, in compliance with a guideline.

(c) A product bearing the statement provided for in paragraph (b) of this section, in addition to meeting the requirements of the applicable nutritional quality guideline or food standard, shall comply with the following requirements:

(1) The label of the product shall bear the common or usual name of the food in accordance with the provisions of the guideline and §§ 1.8 and 102.1 of this chapter and of any applicable food standard promulgated under section 401 of the act.

(2) The label of the product shall bear nutrition labeling in accordance with §§ 1.8d and 1.17 of this chapter and all other labeling required by applicable sections of Part 1 of this chapter.

(d) No claim or statement may be made on the label or in labeling representing, suggesting, or implying any nutritional or other differences between a product to which nutrient addition has or has not been made in order to meet the guideline, except that a nutrient addition shall be declared in the ingredient statement, and except as provided for in guidelines established in Subpart B of this part or in any applicable food standard promulgated under section 401 of the act.

* * * * *

(f) A product within a class of food for which a nutritional quality guideline has been established and to which has been added a discrete nutrient either for which no minimum nutrient level or nutrient range or other allowance has been established as appropriate in the nutritional quality guideline, or at a level that exceeds any maximum established as appropriate in the guideline, shall be ineligible to bear the guideline statement provided for in paragraph (b) of this section, and such a product shall also be deemed to be misbranded under the act unless the label and all labeling bear the following prominent and conspicuous statement: "The addition of _____ to (or "The addition of _____ at the level contained in) this product has been determined by the U.S. Government to be unnecessary and inappropriate and does not increase the dietary value of the food", the blank to be filled in with the common or usual name of the nutrient(s) involved. If the nutrient(s) is added to the product in accordance with § 1.8(e) of this chapter to avoid being an imitation, this paragraph shall not apply.

(g) The following principles shall govern the addition of a vitamin(s), mineral(s), and/or protein to food:

(1) A vitamin, mineral, or protein, as listed in paragraph (g)(3)(v) of this section, may be added to a food which is not naturally a significant source of such nutrient, as defined in § 1.17(c)(7)(v) of this chapter, if all of the following conditions are met:

(i) The intake of the nutrient is below a desirable level in the diets of a significant number of people.

(ii) The food to which the nutrient is added is generally consumed by a significant segment of the population in need.

(iii) The amount of the nutrient added makes a significant contribution to the diet of the population in need.

(iv) The added nutrient is stable in the food under customary conditions of storage and use.

(v) The added nutrient is physiologically available from the food.

(vi) There is a reasonable assurance that an excessive intake which could reach a toxic level will not occur.

(2) A vitamin, mineral, or protein, as listed in paragraph (g)(3)(v) of this section, may be added to a food if addition of the nutrient is necessary to raise the nutritional quality of the food up to the nutritional level appropriate for that food, based upon the best available scientific data on food consumption, nutrition needs, and dietary habits.

(3) Vitamins, minerals, and protein may be added to a food to balance the calorie contribution of the food if all the following conditions are met:

(i) A normal serving of the food contributes at least 56 kilocalories to the diet, i.e., 2 percent of the daily kilocalorie standard of 2800 kilocalories.

(ii) Use of the food reduces the nutritional quality of the total diet when consumer without such added nutrients.

(iii) The added nutrients are physiologically available from the food.

(iv) The food is not the subject of a nutrition quality guideline established in Subpart B of this part or a food standard that prescribes the nutrient additions to the food promulgated under section 401 of the act.

(v) The food with added nutrients, as prepared and eaten by the consumer, contains all of the following nutrients per 100 kilocalories based on 2800 kilocalories per day:

Nutrient	Unit of measurement	Adults and children over 4 yr.	
		U.S. RDA	Per 100 kcal
Protein	Grams	[1] 65.0	2.32
Do	do	45.0	1.61
Vitamin A	IU	5,000.0	179
Vitamin C	Milligrams	60.0	2.14
Thiamine	do	1.5	.054
Riboflavin	do	1.7	.061
Niacin	do	20.0	.72
Calcium	Grams	1.0	.036
Iron	Milligrams	18.0	.64
Vitamin D	IU	400.0	14.3
Vitamin E	do	30.0	1.07
Vitamin B_6	Milligrams	2.0	.071
Folic acid	do	.4	.014
Vitamin B_{12}	µg	6.0	.21
Phosphorus	Grams	1.0	.036
Iodine	µg	150.0	5.36
Magnesium	Milligrams	400.0	14.3
Zinc	do	15.0	.54
Copper	do	2.0	.071
Biotin	do	.3	.011
Panthothenic acid	do	10.0	.357

[1] If the protein efficiency ratio of protein is equal to or better than that of casein, U.S. RDA is 45 g.

(4) A vitamin, mineral, or protein, as listed in paragraph (g)(3)(v) of this section, may be added to a food which is naturally a source of such nutrient if addition of the nutrient is necessary to restore a nutrient shown by adequate scientific documentation to be lost in processing a measurable amount, i.e., at least 2 percent of the U.S. RDA per serving, if the following conditions are met:

(i) The nutrient is shown by adequate scientific documentation to be present in the food prior to processing in a quantity equivalent to at least 2 percent of the U.S. RDA in a normal serving of food.

(ii) Good manufacturing practices cannot avoid a measurable loss in such nutrient during processing.

(iii) The food is not the subject of a nutrition quality guideline established in Subpart B of this part or a food standard that prescribes the addition of nutrients to the food promulgated under section 401 of the act.

(h) Any food to which any vitamin, mineral, or protein has been added shall be deemed to be misbranded under the act unless the label and all labeling bears the prominent and conspicuous statement, "The addition of _____ to (or "The addition of _____ at the level contained in) this product has been determined by the U.S. Government to be unnecessary and inappropriate and does not increase the dietary value of the food" (the blank to be filled in with the common or usual name of the nutrient(s) involved), except for the following:

(1) Any infant food which simulates human milk or is suitable as a complete or partial substitute for human milk and which complies with § 125.5 of this chapter.

(2) Any dietary supplement which complies with § 80.1 and Part 125 of this chapter.

(3) Any food represented for use as the sole item of the diet.

(4) Any food represented for use solely under medical supervision to meet nutritional requirements in specific medical conditions.

(5) Iodized salt.

(6) Any food conforming to a standard of identity promulgated under section 401 of the act.

(7) Any food conforming to a nutritional quality guideline established in Subpart B of this part.

(8) Any food with a vitamin, mineral, or protein restored to preprocessing levels as defined in paragraph (g)(4) of this section.

(9) Any food with a vitamin, mineral, or protein added pursuant to § 1.8(e) of this chapter so that it is not nutritionally inferior to the food for which it substitutes and which it resembles.

(10) Any food fortified in compliance with paragraph (g)(3) of this section.

(11) Any food the composition of which is defined by other regulations or statutes.

(i) The following principles shall govern claims or statements on labels or in labeling:

(1) No claim or statement may be made on the label or in labeling that any vitamin, mineral, or protein has been added to a food, either in general terms, e.g., "fortified", or in specific terms, e.g., "_____ added", if it is added pursuant to § 1.8(e) of this chapter, except that a nutrient addition shall be declared in the ingredient statement.

(2) No claim or statement may be made on the label or in labeling that any vitamin, mineral, or protein has been added to a food, either in general terms, e.g., "fortified", or in specific terms, e.g., "_____ added", unless such vitamin, mineral, protein has been added at a level equal to or in excess of 10 percent of the U.S. RDA in a serving (or portion) of the food, except that a nutrient addition shall be declared in the ingredient statement.

(3) A food with a vitamin(s), mineral(s), or protein restored to preprocessing levels as defined in paragraph (g)(4) of this section may be labeled as "_____ restored" with the blank filled in with the vitamin(s), mineral(s), or protein restored if such vitamin(s), mineral(s), or protein has been added at a level equal to or in excess of 10 percent of the U.S. RDA in a serving (or portion) of the food.

(4) The label of a food to which vitamins, minerals, and protein have been added in accordance with paragraph (g)(3) of this section may bear the statement "Contains vitamins, minerals, and protein in proportion to its caloric content".

(j) For the purposes of food labeling, the following definitions shall apply:

(1) "Enriched" or "enrichment" means the addition to a food or one or more vitamin(s), mineral(s), or protein(s) which are naturally present in lesser amounts in the food in order to increase the consumption of such nutrient(s) by the general population or a specific segment of the population.

(2) "Restoration" means the addition of one or more vitamin(s), mineral(s), or protein(s) to a processed food in order to restore such nutrient(s) lost during processing to the level naturally present in the unprocessed food.

(3) "Fortification" or "fortified" means the addition to a food of one or more vitamin(s), mineral(s), or protein(s) not naturally present in the food in order to increase the consumption of such nutrient(s) by the general population or by a specific segment of the population. When the added nutrients include at least one nutrient not naturally present and one or more nutrients naturally present, the term "fortification" or "fortified" applies.

Interested persons may, on or before August 13, 1974, file with the Hearing Clerk, Food and Drug Administration, Rm. 6-86, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: June 7, 1974.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.74-13469 Filed 6-13-74;8:45 am]

[21 CFR Parts 100, 102]

FORMULATED MEAL REPLACEMENTS

Proposed Nutritional Quality Guideline and Common or Usual Name

In the FEDERAL REGISTER of March 14, 1973 (38 FR 6969), the Commissioner of Food and Drugs promulgated a procedure and general principles for the establishment by regulation of nutritional quality guidelines for foods; and he set forth general principles for establishing common or usual names for nonstandardized foods (21 CFR 102.1).

NUTRITION GUIDELINE

The Commissioner had earlier contracted with the National Academy of Sciences for assistance in identifying and defining the important classes of foods for which such nutritional quality guidelines should be established and in providing proposed nutrient compositions for them which would be in the best interest of the public health. The recommendations of the Committee on Food Standards and Fortification Policy of the National Academy of Sciences/National Research Council (the NAS/NRC Committee) for formulated meal replacements have been received by the Commissioner. A copy of this report is on public display at the office of the Hearing Clerk, Food and Drug Administration, Rm. 6-86, 5600 Fishers Lane, Rockville, MD 20852.

The Commissioner has reviewed this report and proposes a nutritional quality guideline for formulated meal replacements based upon the recommendations of the NAS/NRC Committee. Formulated meal replacements are those products which are represented for use as the sole source of nutrients for one or two meals per day but not as the sole item of the diet. Formulated meal bases to which other food components are added may be considered formulated meal replacements when finally constituted for consumption if the labeling of the product clearly indicates that other food components must be added. The two proposals do not include those food products represented for use as the sole item of the diet or for use solely under medical supervision to meet nutritional requirements in specific medical conditions. Such foods are special dietary foods subject to 21 CFR Part 125.

The NAS/NRC Committee concluded, and the Commissioner agrees, that, because of the consumer's reliance on the meal replacement as a major source of his total nutrient intake, it is necessary to assure a more complete spectrum of essential nutrients in meal replacements than in other classes of foods.

Althought the NAS/NRC Committee report stated that these meal replacements should not be intended for use as a sole dietary item for extended periods, the Commissioner is aware that, while not intended or represented for such use, these products may be used in this manner by some indivduals. The Commissioner has therefore included in the guideline nutrients not considered by the NAS/NRC Committee, and in some cases the levels of nutrients have been increased.

The NAS/NRC Committee recommended that nutrients be present in formulated meal replacements at levels corresponding to a minimum of 25 percent and a maximum of 50 percent of the "mean RDA for both sexes from age 3 to 75" per average serving. The Commissioner accepts the NAS/NRC Committee's recommendation, but proposes to use the U.S. RDA as the reference standard for the reasons outlined in the preamble to the nutrition labeling proposal published in the FEDERAL REGISTER of January 19, 1973 (38 FR 2125). In most cases, the U.S. RDA values are somewhat higher than the "mean RDA". The upper limit of 50 percent is only applicable to those nutrients added as discrete entities. Requirements for manganese and potassium have also been included even though U.S. RDA's have not been established. The levels of these nutrients are based upon amounts of the nutrients obtained from diets of conventional foods.

The NAS/NRC Committee recommended using protein with a protein efficiency ratio (PER) of not less than 80 percent that of casesin. It also suggested a formula for adjusting the protein quantity to compensate for a PER below 80 percent that of casein.

The Commissioner concludes that, since these products may be used as meal replacements for extended periods of time, the protein quality takes on added significance. The U.S. RDA for protein was established presuming consumption of a mixture of protein sources. When formulated meal replacements are used as the sole source of protein in the diet, such a mixture of proteins may not be provided. The adjustment formula presented by the NAS/NRC Committee is complex and not considered practicable for regulatory purposes. The Commissioner proposes to require the protein in formulated meal replacements to have a PER of at least 80 percent that of casein. The quantity of protein will be the same as that established in the U.S. RDA for protein, i.e., 65 grams for protein with a PER value less that that of casein and 45 grams for protein with a PER value equal to or greater than casein.

The NAS/NRC Committee recommended that, if fat is included in the formulation, the product provide at least 2 percent of the total calories as linoleic acid. The Commissioner agrees with the recommendation and, since he understands that all of these products are formulated to contain fat, he therefore proposes that formulated meal replacements provide 2 percent of the total calories of the product as linoleic acid to supply essential fatty acids.

A minimum calorie level was not given in the NAS/NRC Committee report but the different uses of formulated meal replacements were identified. The Commissioner proposes to establish a minimum calorie level of 700 kilocalories (kcal), unless the product is represented for use in a reduced calories diet. The Commissioner believes that this is an appropriate caloric value in that it represents ¼ of the daily calorie standard proposed in the "General Principles Governing the Addition of Nutrients to Foods" published elsewhere in this issue of the FEDERAL REGISTER.

The NAS/NRC Committee recommended that, to avoid undue dilution of nutrients when a meal replacement has a high caloric content, 100 kcal of a product shall contain not less than the mean RDA/100 kcal for all nutrients required to be present. The Commissioner has decided instead to establish minimum nutrient levels per serving which will insure sufficient nutrients in each meal replacement.

The NAS/NRC Committee excluded biotin because biotin deficiencies are so rarely encountered. Biotin has, however, been added to the proposed guideline since these meal replacement products may, in fact, be used as dietary items for rather extended periods, particularly in reduced calorie diets.

Sodium and chloride were excluded by the NAS/NRC Committee because of the remote likelihood of an inadequate intake. The guideline also excludes sodium and chloride from the required list of nutrients, but does require the labeling to list the sodium content in accordance with § 1.17(c)(6)(iv) (21 CFR 1.17(c)(6)(iv)). Sodium content, normally an optional declaration, is mandatory in this case because this class of foods often contains high levels of sodium as a result of processing, and it is important that this information be available to the consumer at the point of purchase.

COMMON OR USUAL NAME

There are numerous products in the marketplace and others in development which are functional meal replacements or substitutes for meals either as convenience foods, aids in weight control, meal adjuncts or snacks. This class of food is unique in that it has an essentially complete and balanced nutrient composition. Copies of representative labels of these products are on public display in the office of the Hearing Clerk.

To identify these products the Commissioner proposes the establishment of common or usual names for them under Part 102 (21 CFR Part 102).

It is essential that a common or usual name for such products be general enough to include all of the wide variety of products that may be offered as meal replacements (but not diet replacements) and yet sufficiently specific that such products can be readily identified. The Commissioner is therefore proposing that the common or usual name of these products be "formulated meal replacement". When it is necessary to add other foods to the product in order for it to be nutritionally equivalent to the meal it is replacing, it is proposed that the common or usual name consist of the term (1) "formulated meal base" and (2) an appropriate informative statement that additional ingredient(s) or component(s) must be added and which

names the additional ingredient(s) or component(s).

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201(n), 403, 701(a), 52 Stat. 1041, 1047–1048 as amended, 1055; 21 U.S.C. 321(n), 343, 371(a)) and under authority delegated to the Commissioner (21 CFR 2.120), it is proposed that Chapter I of Title 21 of the Code of Federal Regulations be amended:

1. In Part 100 by adding thereto the following new section:

§ 100.8 Formulated meal replacements.

(a) A product, for which a common or usual name is established in § 102.21 of this chapter, to be eligible to bear the guideline statement set forth in § 100.1 (b), shall be formulated so that a serving meets the following requirements:

(1) It contains all nutrients listed in paragraph (b) of this section in an amount not less than 25 percent of the U.S. RDA. When a discrete nutrient is added in order to meet the requirements of the guideline, the total amount of that nutrient per serving shall not exceed 50 percent of the U.S. RDA for that nutrient.

(2) It contains no less than 1 milligram and no more than 2 milligrams of manganese and no less than 1 gram and no more than 2 grams of potassium.

(3) It supplies a minimum of 700 kilocalories (kcal), except that if the product is represented for use in a reduced calorie diet this minimum shall not apply.

(4) It provides at least 2 percent of the total calories as linoleic acid.

(5) It provides protein with an overall protein efficiency ratio of not less than 80 percent of that of casein.

(b) The following nutrients are required to be present at the levels specified in paragraph (a)(1) of this section.

Nutrient	*U.S. RDA*
Protein (grams)	65 or 45 in accordance with § 1.17(c)(7)(ii)(*a*) of this chapter.
Vitamin A (IU)	5,000.
Vitamin C (milligrams)	60.
Thiamine (milligrams)	1.5.
Riboflavin (milligrams)	1.7.
Niacin (milligrams)	20.
Calcium (grams)	1.
Iron (milligrams)	18.
Vitamin B_6 (milligrams)	2.
Folic acid (milligrams)	0.4.
Vitamin B_{12} (μg)	6.
Phosphorus (grams)	1.
Iodine (μg)	150.
Magnesium (milligrams)	400.
Zinc (milligrams)	15.
Copper (milligrams)	2.
Vitamin D (IU)	400.
Vitamin E (IU)	30.
Biotin (milligrams)	0.3.
Pantothenic acid (milligrams)	10.

(c) All nutrients listed in paragraph (b) of this section shall be labeled in accordance with § 1.17(c)(7) of this chapter.

(d) The sodium content shall be labeled in accordance with § 1.17(c)(6)(iv) of this chapter.

(e) Manganese and potassium content shall be labeled following the sodium content and shall be declared in milligrams per 100 grams of the food.

(f) Any product which is represented for use in a reduced calorie diet shall be labeled in accordance with § 125.6 of this chapter.

(g) A serving shall be the amount that, when finally constituted for consumption, is intended to replace a single meal.

2. In Part 102 by adding thereto the following new section:

§ 102.21 Formulated meal replacements/or bases.

(a) The common or usual name of a packaged food, including the liquid, dry, or solid forms, which is in its final form for consumption or to which only water need be added and which is represented as being a nutritionally adequate replacement for one or two meals per day, shall be "formulated meal replacement".

(b) The common or usual name of a packaged food, to which one or more food components (other than water) must be added, e.g., milk, to make a food that, when finally constituted for consumption, is represented as a nutritionally adequate replacement for one or two meals per day, shall consist of the following:

(1) The name "formulated meal base".

(2) An appropriate informative statement that additional ingredient(s) or component(s) must be added and which names the additional ingredient(s) or component(s) in accordance with the requirements of § 102.1(c)(2) and (3), e.g., "you must add _____" the blank to be filled in with the name(s) of the ingredient(s) or component(s) that must be added.

(c) This section shall not apply to any food represented for use as the sole item of the diet or for use solely under medical supervision to meet nutritional requirements in specific medical conditions.

Interested persons may, on or before August 13, 1974, file with the Hearing Clerk, Food and Drug Administration, Rm. 6–86, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: June 7, 1974.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.74–13478 Filed 6–13–74;8:45 am]

[21 CFR Parts 100 and 102]

MAIN DISH PRODUCTS

Proposed Nutritional Quality Guideline and Common or Usual Name

In the FEDERAL REGISTER of March 14, 1973 (38 FR 6964, 6969), the Commissioner of Food and Drugs promulgated a procedure and general principles for the establishment by regulation of nutritional quality guidelines for foods and general principles and procedure for establishing common or usual names for classes of foods.

NUTRITIONAL GUIDELINE

The Commissioner had earlier contracted with the National Academy of Sciences for assistance in identifying and defining the important classes of foods for which such nutritional quality guidelines should be established and in providing proposed nutrient compositions for them which would be in the best interest of the public health. The recommendations of the Committee on Food Standards and Fortification Policy of the National Academy of Sciences/National Research Council (the NAS/NRC Committee) for main dish products have been received by the Commissioner. A copy of this report is on public display in the office of the Hearing Clerk, Food and Drug Administration, Rm. 6–86, 5600 Fishers Lane, Rockville, MD 20852.

The Commissioner has reviewed this report and proposes to establish a nutritional quality guideline for main dish products based upon the recommendations of the NAS/NRC Committee.

The NAS/NRC Committee has selected three subclasses of main dish products for establishment of nutritional guidelines. It was reasoned that, because of the large variety of main dish products possible, subclasses were appropriate in that certain main dishes provide different patterns of nutrients than others and that subclass guidelines would define more appropriately the minimum nutrient levels than a single set of values.

The Commissioner agrees and the proposed guideline incorporates this concept. The proposal establishes minimum nutrient levels for three subclasses of main dish products intended to be used as a principal part of a meal: macaroni or noodles and cheese, main dish pies and pizza, and combination recipes. The nutrient levels established for these subclasses differ slightly, consistent with the principal food components used.

The NAS/NRC Committee recommended that whenever flour or macaroni or noodle products are used they be enriched so that the addition of discrete nutrients will be minimized. The proposed guideline does not incorporate this as a requirement, but it is expected that manufacturers will use the enriched products when needed to meet a guideline nutrient(s) level.

The NAS/NRC Committee report divides main dishes into two general classes depending on what percent of the primary protein source is in the form of fabricated protein analogues. The pres-

ent proposal does not include a separate guideline for foods using plant protein products. The common or usual name of plant protein products in finished food is the subject of a proposal published elsewhere in this issue of the FEDERAL REGISTER. Any main dish product utilizing a plant protein product as an extender or replacement of a traditional source of protein therefore will also be subject to the labeling requirements of that regulation. Plant protein products added as a significant source of protein, but not in the form of a traditional source of protein, would also be labeled as a characterizing component in accordance with the provisions of the proposed common or usual name for main dish products.

The NAS/NRC Committee included beans as one of the sources of protein to be used in certain main dish products. The Commissioner realizes that beans and other legumes contain significant quantities of protein; however, their protein quality (i.e., protein efficiency ratio (PER)) is significantly lower than the other protein sources listed. The Commissioner concludes that it would be more appropriate to eliminate beans as a source of protein for products meeting the guideline rather than include a protein quality specification in the guideline.

The NAS/NRC Committee recommended that, if a nutrient is added as a discrete chemical entity in order to achieve guideline levels of nutrients, the level of the nutrient shall not exceed 200 percent of the level recommended by the guideline. It also recommended that the addition of no more than two discrete nutrients be allowed to products in this class. The proposed guideline does not include a maximum number of discrete nutrients that can be added to a product and has reduced the maximum level of nutrients permitted (when such nutrients are added) to 150 percent of the level recommended by the guideline. The reasons for this are the same as those expressed in the preamble to the nutritional quality guideline on frozen heat and serve dinners published in the FEDERAL REGISTER of March 14, 1973 (38 FR 6969).

COMMON OR USUAL NAME

There is a large number of packaged, frozen, canned, or dry mix products on the market that are intended as the principal part of a meal. These main dish products, like frozen heat and serve dinners, through consumer usage have assumed a significant role in shaping nutrition patterns in the American diet. Representative labels of these products are on display in the office of the Hearing Clerk.

In order to distinguish between the various types of main dish products available, it is proposed that the name of the food include the major components of the product and that the main dish product contain at least one significant protein source and one or more vegetables, fruit, potatoes, rice, or other cereal-based product.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201(n), 403, 701(a), 52 Stat. 1041, as amended, 1047–1048, as amended, 1055 (21 U.S.C. 321(n), 343, 371(a))) and under authority delegated to the Commissioner (21 CFR 2.120), it is proposed that Chapter I of Title 21 of the Code of Federal Regulations be amended as follows:

1. In Part 100 by adding the following new section to Subpart B:

§ 100.7 Main dish products.

(a) A product, for which a common or usual name is established in § 102.20 of this chapter, in order to be eligible to bear the guideline statement set forth in § 100.1(b):

(1) Shall be prepared from (i) at least one source of protein derived from meat, poultry, fish (seafood), cheese, eggs, or an appropriate plant protein product meeting the requirements of § 102.22 of this chapter and (ii) one or more vegetables, fruit, potatoes, rice, or other cereal-based products; and

(2) Shall be constituted so as to conform with the requirements of the appropriate subclass of main dish products listed in paragraph (b) of this section.

(b) Three main dish product subclasses are established as follows:

(1) Macaroni or noodles and cheese. This subclass contains cheese as the major source of protein and a form of a macaroni or noodle product.

(2) Pies and pizzas. This subclass contains a major source(s) of protein derived from meat, plant protein product, poultry, fish (seafood), cheese, or eggs; vegetable(s), pastry, bread dough shell, or crust top.

(3) Combination recipes. This subclass contains a source of protein derived from meat, plant protein product, poultry, fish (seafood), cheese, or eggs; one or more vegetables, fruit, potatoes, rice, or other cereal-based products. This subclass does not include main dish pies or pizza identified in paragraph (b)(2) of this section.

(c) The subclasses of main dish products identified in paragraph (b) of this section, including their sauces, gravies, breadings, etc., but excluding any other food ingredient added at the time of preparation, shall contribute not less than the minimum levels of nutrients prescribed below:

Nutrient	Minimum levels for main dish products for each 100 kcal		
	Macaroni or noodles and cheese	Pies and pizza	Combination recipes
Protein (grams)	3.5	3.5	4.6
Vitamin A (IU)	150.0	200.0	300.0
Thiamine (milligrams)	.038	.05	.05
Riboflavin (milligrams)	.075	.06	.06
Niacin (milligrams)	.66	1.0	1.0
Iron (milligrams)	.47	.62	.62
Calcium (milligrams)	68.0	(1)	(1)

[1] See par. (c)(3) of this section.

(1) Main dish products prepared from conventional food ingredients listed in paragraph (a) of this section will be expected to contain vitamin B_6, vitamin B_{12}, folic acid, magnesium, pantothenic acid, and zinc. Minimum levels for these nutrients cannot be established at the present time but will be added as additional data are obtained.

(2) When technologically practicable, iodized salt shall be used or iodine shall be present at a level equivalent to that which would be present if iodized salt were used in the manufacture of the product.

(3) When technologically practicable, product components and ingredients shall be selected to obtain the desirable calcium to phosphorus ratio of 1:1. Technological addition of phosphates shall be minimized and shall not exceed the amount necessary for the intended effect.

(d) If it is necessary to add any nutrient(s) in order to meet the minimum nutrient levels prescribed in paragraph (c) of this section, the addition of each such nutrient shall not result in a total nutrient level exceeding 150 percent of the minimum level prescribed. Nutrients used for such addition shall be biologically available in the final product.

2. In Part 102 by adding the following new section to Subpart B:

§ 102.20 Main dish products.

(a) A main dish product shall contain (1) a significant source of protein and (2) one or more vegetables, fruit, potatoes, rice, or other cereal-based products, intended to be eaten together as a single food.

(b) The common or usual name of the food shall consist of all of the following:

(1) An appropriately descriptive term for the dish, e.g., macaroni and cheese, pizza, tuna casserole, etc.

(2) The phrase "containing (or contains) _____", the blank to be filled in with an accurate description of each of the characterizing component(s) of the product in their order of descending predominance by weight. This part of the name shall be placed immediately following the part specified in paragraph (b)(1) of this section in the manner set forth in § 102.1(c)(3). The word "contains" or "containing" is optional. This element of the common or usual name will not be required for those products that include the characterizing components of the product in order of predominance in that part of the name required by paragraph (b)(1) of this section, e.g., "macaroni and cheese mix" will not be required to state "contains macaroni and cheese".

(3) If the dish is frozen, the term "frozen" shall immediately precede the part of the name specified in paragraph (b)(1) of this section unless the words "Keep Frozen" or the equivalent are prominently and conspicuously placed on the principal display panel in type size not less than that specified in § 102.1(b)(2)(i).

Interested persons may, on or before August 13, 1974, file with the Hearing Clerk, Food and Drug Administration, Rm. 6–86, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably

in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: June 7, 1974.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.74-13475 Filed 6-13-74;8:45 am]

[21 CFR Part 102]

DILUTED FRUIT OR VEGETABLE JUICE BEVERAGES

Proposed Common or Usual Names for Nonstandardized Foods

In an order published in the FEDERAL REGISTER of March 14, 1973 (38 FR 6964), the Commissioner of Food and Drugs established a procedure and general principles for the establishment by regulation of common or usual names for foods. Elsewhere in the same issue of the FEDERAL REGISTER, pursuant to this procedure, the Commissioner established a common or usual name for diluted orange juice beverages (38 FR 6968).

The justification for establishing the common or usual name for diluted orange juice beverages also exists with respect to the diluted juices of other fruits and vegetables, including combinations of orange juice with other juices. The amount of juice present in the beverage is the major factor determining the price and consumer acceptance of the product. Observation of most labels on diluted juice products currently found on retail market shelves shows that consumers are not being informed in regard to the amount of juice present in diluted juice products (representative labels demonstrating this fact are on public display in the office of the Hearing Clerk).

The Commissioner concludes that consumer confusion can be significantly lessened by adoption of informative common or usual names which include a declaration of the percent of juice(s) present in all diluted fruit or vegetable juice beverages.

Orders were published in the FEDERAL REGISTER of April 11 and May 7, 1968 (33 FR 5617 and 6862), establishing standards of identity for certain diluted fruit juice beverages. Objections were filed to the orders, and subsequently orders were published in the FEDERAL REGISTER of July 13 and 27, 1968 (33 FR 10088 and 10713), staying the effective dates of the standards. In a notice published in the FEDERAL REGISTER of September 9, 1971 (36 FR 18098), the Commissioner proposed to amend the stayed standards. The stays are still in effect. However, the Commissioner concludes that a separate regulation should be proposed at this time, pursuant to 21 CFR Part 102, establishing the percent of juice present as part of the common or usual name for diluted juice beverages made from fruits and vegetables other than only oranges and is setting forth in proposed § 102.23(b) a general method for calculating the percentage of juice in a beverage.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201(n), 403, 701(a); 52 Stat. 1041, as amended, 1047–1048, as amended, 1055 (21 U.S.C. 321(n), 343, 371(a))) and under authority delegated to the Commissioner (21 CFR 2.120), it is proposed that Part 102 be amended by adding a new section as follows:

§ 102.23 Diluted fruit or vegetable juice beverages other than diluted orange juice beverages.

(a) The common or usual name of a noncarbonated beverage containing less than 100 percent and more than 0 percent fruit or vegetable juice(s), other than only orange juice, shall be as follows:

(1) A descriptive name meeting the requirements of § 102.1(a) (e.g., "diluted grape juice beverage" or another descriptive phrase) and

(2) A statement of the percent of each juice contained in the product in the manner set forth in § 102.1(b)(2). The percent of juice shall be declared in 5-percent increments, expressed as a multiple of five not greater than the actual percentage of juice in the product, except that the percent of any juice in products containing more than 0 percent but less than 5 percent of that juice shall be declared in the statement as "less than 5" percent.

(b) The percent of fruit or vegetable juice(s) in a diluted product is calculated on the basis of the soluble solids content of the single strength (undiluted) juice used to prepare the diluted juice(s). If the finished food is prepared from concentrated juice(s), the percent of fruit or vegetable juice(s) is calculated on the basis of the soluble solids content of the single strength (unconcentrated) juice(s) used to produce such concentrated juice(s).

Interested persons may, on or before August 13, 1974, file with the Hearing Clerk, Food and Drug Administration, Room 6–86, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum of brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: June 7, 1974.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.74-13480 Filed 6-13-74;8:45 am]